APPENDIX 18: CLINICAL EVIDENCE – STUDY CHARACTERISTICS TABLES

1.1 CASE IDENTIFICATION – INCLUDED STUDIES

1.1.1 ADEWUYA2005

Study ID	ADEWUYA2005
Bibliographic reference	Adewuya AO, Eegunranti AB, Lawal AM. Prevalence of postnatal depression in Western Nigerian women: a controlled study. International Journal of Psychiatry in Clinical Practice. 2005;9:60-4
Clinical features and settings	**Recruitment:** Postnatal clinic and immunisation clinics at 5 health centres. **Timing:** Postnatal (6 weeks) **Country:** Nigeria **Language:** English or Yoruba **Recruitment location:** Postnatal clinic and immunisation clinics at 5 health centres
Participants	**N =** 876 **Age:** 29 **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Major depression and combined major and minor depression.
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** DSM-IIR, SCID-NP **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Prevalence	14.6%
Index cut-off	9/10
Limitations	
Source of funding	Not stated
Notes	

1.1.2 ADEWUYA2006

Study ID	ADEWUYA2006
Bibliographic reference	Adewuya AO, Ola BA, Dada AO, Fasoto OO. Validation of the Edinburgh Postnatal Depression Scale as a screening tool for depression in late pregnancy among Nigerian women.Journal of Psychosomatic Obstetrics and Gynecology. 2006;27(4):267-272.
Clinical features and settings	**Recruitment:** Antenatal clinics at five health centres. **Time:** Pregnancy (+32 weeks) **Country:** Nigeria **Langauge:** Enlish or Yoruba **Recruitment location:** Antenatal clinics
Participants	**N =** 182 (86 cases[1]) **Age:** 25
Study design	Cross-sectional case-control
Target condition	Major depression and combined major and minor depression.
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** Mini DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Prevalence	17.4% (major and minor) 10.5%(major depression)
Index cut-off	
Limitations	
Source of funding	Not stated
Notes	[1]Number noted in study who completed EPDS.

1.1.3 AGOUB2005

Study ID	AGOUB2005
Bibliographic reference	Agoub M, Moussaoui D, Battas O. Prevalence of postpartum depression in a Moroccan sample. Archives of Women's Mental Health. 2005;8:37-43
Clinical features and settings	**Recruitment:** Maternal and infantile health unit in a primary healthcare setting **Timing:** Postnatal (2, 6 weeks, 6,9 months) **Country:** Nigeria **Langauge**: Arabic Recruitment location: Maternal and infantile health unit in a primary healthcare setting
Participants	**N =** 144 **Mean age (SD):** 30 **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** Mini DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Unclear
Prevalence	18.8%
Index cut-off	Unclear
Limitations	
Source of funding	Not stated
Notes	N/A

1.1.4 ALVARADE-ESQUIVEL2006

Study ID	ALVARADO-ESQUIVEI2006
Bibliographic reference	Alvarado-Esquivel C, Sifuentes-Alvarez A, Salas-Martinez C, Martínez-García S. Validation of the Edinburgh Postpartum Depression Scale in a population of puerperal women in Mexico. Clinical Practice and Epidemiology in Mental Health. 2006;2:33.
Clinical features and settings	**Recruitment:** Postnatal consultations, public hospital **Timing:** Postnatal (Group 1<4 weeks>Group 2>13 weeks) **Country:** Mexico
Participants	**N =** 100 (Group 1=49, Group 2=51) **Mean age:** 24 **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Unclear[1]
Index cut-off	Unclear
Limitations	Risk factors- low socioeconomic status
Source of funding	Not stated
Notes	[1]Calculated from ROC scores

1.1.5 ASCASO2003

Study ID	**ASCASO2003**
Bibliographic reference	Ascaso Terren C, Garcia Esteve L, Navarro P, Aguado J, Ojuel J, Tarragona MJ. Prevalence of postpartum depression in Spanish mothers: comparison of estimation by mean of the structured clinical interview for DSM-IV with the Edinburgh Postnatal Depression Scale. Medicina Clinica. 2003;120:326-329.
Clinical features and settings	**Recruitment:** Antenatal clinics **Timing:** Pregnancy (6 months) Postnatal (3, 12 months) **Country:** Portugal
Participants	**N =** 334 **Mean age (SD):** 25.0 y (N/R) **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** SADS **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Unclear
Index cut-off	
Limitations	
Source of funding	
Notes	

1.1.6 AYDIN2004

Study ID	**AYDIN2004**
Bibliographic reference	Aydin N, Inandi T, Yigit A, Hodoglugil NN. Validation of the Turkish version of the Edinburgh Postnatal Depression Scale among women within their first postpartum year.Social Psychiatry and Psychiatric Epidemiology. 2004;39(6):483-6
Clinical features and settings	**Recruitment:** Primary health care clinics **Timing:** Postnatal **Country:** Portugal
Participants	**N =** 341[1] **Mean age (SD):** 26.6 y (4.8) **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS – 10 item **2.Reference Standard:** DSM-IV, SCID-I **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Mental health professional
Index cut-off	+12.5
Limitations	
Source of funding	Not reported
Notes	[1]No previous psychiatric treatment history

1.1.7 BAGGALEY2007

Study ID	**BAGGALEY2007**
Bibliographic reference	Baggaley RF, et al. "Short communication: Detecting depression after pregnancy: The validity of the K10 and K6 in Burkina Faso." Tropical Medicine and International Health. 2007;12:1225-1229.
Clinical features and settings	**Recruitment:** N/R **Timing:** Postnatal **Country:** Burkina Faso
Participants	**N =** 61 **Mean age:** 26 **Ethnicity:** Not stated
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** Kessler-10 **2.Reference Standard:** ICD-10 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Index cut-off	
Limitations	Sampling favoured women with higher k10 scores
Source of funding	Not reported
Notes	[1]No previous psychiatric treatment history

1.1.8 BARNETT1999

Study ID	**BARNETT1999**
Bibliographic reference	Barnett B, Matthey S, Gyaneshwar R. Screening for postnatal depression in women of non-English speaking background. Archives of Women's Mental Health. 1999;2:67-74.
Clinical features and settings	**Recruitment:** N/R **Timing:** Postnatal (6 week, 6 months) **Country:** Australia
Participants	**N =** 316 (Anglo-celtic = 105, Arabic = 98, Vietnamese = 113) **Mean age (SD):** N/R **Ethnicity:** See above.
Study design	Cross-sectional cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:** DIS DSM-IIIR **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Research assistants
Index cut-off	
Limitations	ADD
Source of funding	Commonwealth Department of Health, Housing and Community Services
Notes	

1.1.9 BECK2001

Study ID	**BECK2001**
Bibliographic reference	Beck CT, Gable RK. Comparative analysis of the performance of the Postpartum Depression Screening Scale with two other depression instruments. Nursing Research. 2001;50:242-250.
Clinical features and settings	**Recruitment:** Childbirth classes or newspaper adverts **Timing:** Postnatal **Country:** US
Participants	**N=**150 [1] **Mean age:** 31 **Ethnicity:** See above.
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression only
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:** DSM-IV, SCID. **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Blind nurse psychotherapist
Index cut-off	Multiple
Limitations	
Source of funding	The Patrick and Catherine Weldon Donaghue Medical Research Foundation and the University of Connecticut Research Foundation
Notes	[1]2-12 weeks Postnatal

1.1.10 BENVENUTI999

Study ID	**BENVENUTI1999**
Bibliographic reference	Benvenuti P, Ferrara M, Niccolai C, Valoriani V, Cox JL. The Edinburgh Postnatal Depression Scale: Validation for an Italian sample. Journal of Affective Disorders. 1999;53:137-141.
Clinical features and settings	**Recruitment:** Obstetric Clinic **Timing:** Postnatal **Country:** Italy
Participants	**N=**32 **Mean age (SD):** 32 **Ethnicity:** See above.
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression only
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:** MINI DSM-IIIR **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.11 BERGINK2011

Study ID	**BERGINK2011**
Bibliographic reference	Bergink V, Kooistra L, Lambregtse-van den Berg MP, Wijnen H, Bunevicius R, van Baar A, Pop V. Validation of the Edinburgh Depression Scale during pregnancy. Journal of Psychosomatic Research. 2011;70:385-389.
Clinical features and settings	**Recruitment:** Community midwife practices **Timing:** Pregnancy (12 weeks) **Country:** The Netherlands
Participants	**N=**854 **Mean age:** 30 **Ethnicity (% caucasian):**1
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression only
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**CID **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	

Source of funding	ADD
Notes	

1.1.12 BERLE2003

Study ID	**BERLE2003**
Bibliographic reference	Berle JO, Aarre TF, Mykletun A, Dahl AA, Holsten F. Screening for postnatal depression: Validation of the Norwegian version of the Edinburgh Postnatal Depression Scale, and assessment of risk factors for postnatal depression. Journal of Affective Disorders. 2003;76:151-156.
Clinical features and settings	**Recruitment:** Routine Postnatal visits – check location **Timing:** Postnatal (6-12 weeks) **Country:** Norway
Participants	**N=**100[1] **Mean age (SD):** 30 **Ethnicity (% caucasian):**1
Study design	Cross-sectional case-control
Target condition	Combined major and minor depression only
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**MINI DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	[1]EPDS score +8 and every 10th subthreshold case.

1.1.13 BOYCE1993

Study ID	**BOYCE1993**
Bibliographic reference	Boyce P, Stubbs J, Todd A. The Edinburgh Postnatal Depression Scale: Validation for an Australian sample. Australian and New Zealand Journal of Psychiatry. 1993;27:472-476.
Clinical features and settings	**Recruitment:** Mothers' Advisory Clinics and outpatient psychiatric referalls **Timing:** Postnatal (<6months) **Country:** Australia
Participants	**N=**103 **Mean age:** 28 **Ethnicity: N/R**
Study design	Cross-sectional case-control
Target condition	Major depression only
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**SPI RDC **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	Women referred to outpatient psychiatric services were also included.
Source of funding	ADD
Notes	

1.1.14 BUNEVICIUS2009

Study ID	**BUNEVICIUS2009**
Bibliographic reference	Bunevicius A, Kusminskas L, Pop VJ, Pedersen CA, Bunevicius R. Screening for antenatal depression with the Edinburgh Depression Scale. Journal of Psychosomatic Obstetrics and Gynecology. 2009;30(4):238-43
Clinical features and settings	**Recruitment:** Mothers' Advisory Clinics and outpatient psychiatric referalls **Timing:** Pregnancy (no limitations) **Country:** Lithuania
Participants	**N=**230 **Mean age:** 29 **Ethnicity:** N/R
Study design	Cross-sectional cohort
Target condition	Both major depression and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**DSM-III-R, SCID-NP **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	

Source of funding	ADD
Notes	

1.1.15 CARPINIELLO1997

Study ID	**CARPINIELLO1997**
Bibliographic reference	Carpiniello B, Pariante CM, Serri F, Costa G, Carta MG. Validation of the Edinburgh postnatal depression scale in Italy.Journal of Psychosomatic Obstetrics and Gynaecology. 1997;18(4):280-5
Clinical features and settings	**Recruitment:** Obstetrics Clinic **Timing:** Postnatal (all women admited for delivery) **Country:** Italy
Participants	**N=**61 **Mean age:** 32 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major depression and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**PSE PSE-ID-Catego **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.16 CHAUDRON2010

Study ID	**CHAUDRON2010**
Bibliographic reference	Chaudron LH, Szilagyi PG, Tang W, Anson E, Talbot NL, Wadkins HI, Tu X, Wisner KL. Accuracy of depression screening tools for identifying postpartum depression among urban mothers. Pediatrics. 2010;125:e609-17
Clinical features and settings	**Recruitment:** WCC visits **Timing:** Postnatal (1st year) **Country:** US
Participants	**N=**61[1] **Mean age (SD):** 32y (ADD SD) **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major depression and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**DSM-IV (SCID) **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD

Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	[1]Low income, urban mothers

1.1.17 CHIBANDA2010

Study ID	**CHIBANDA2010**
Bibliographic reference	Chibanda D, Mangezi W, Tshimanga M, Woelk G, Rusakaniko P, Stranix-Chibanda L, et al. Validation of the Edinburgh Postnatal Depression Scale among women in a high HIV prevalence area in urban Zimbabwe. Archives of Women's Mental Health. 2010;13(3):201-6
Clinical features and settings	**Recruitment:** Routine postnatal checkups **Timing:** Postnatal (6-7 weeks) **Country:** Zimbabwe
Participants	**N=**210 **Mean age (SD):** 25 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.18 CLARKE2008

Study ID	**CLARKE2008**
Bibliographic reference	Clarke PJ. Validation of two postpartum depression screening scales with a sample of First Nations and Metis women. The Canadian Journal of Nursing Research. 2008;40:113-25.
Clinical features and settings	**Recruitment:** Postnatal and parenting groups **Timing:** Postnatal (<12months) **Country:** Canada
Participants	**N=**103 **Mean age (SD):** 24 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major and minr depression (only)
Index and comparator	**1.Instrument:** EPDS-10

tests	**2.Reference Standard:**SCID DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.19 COX1987

Study ID	COX1987
Bibliographic reference	Cox JL, Holden JM, Sagovsky R. Detection of Postnatal Depression: development of the 10-item Edinburgh Postnatal Depression scale. British Journal of Psychiatry. 1987;150:782-6.
Clinical features and settings	**Recruitment:** Health visitors **Timing:** Postnatal (6 weeks) **Country:** UK
Participants	**N=**96 (cases=84[1], control=12) **Mean age (SD):** 24 **Ethnicity: N/R**
Study design	Cross-sectional case-control
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**SPI RDC **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	[1]Identified as high risk.

1.1.20 EBERHARD-GRAND2001

Study ID	**EBERHARD-GRAND2001**
Bibliographic reference	Eberhard-Gran M, Eskild A, Tambs K, Schei B, Opjordsmoen S. The Edinburgh Postnatal Depression Scale: validation in a Norwegian community sample. Nordic Journal of Psychiatry. 2001;55:113–7.
Clinical features and settings	**Recruitment:** Community-based child health clinics **Timing:** Postnatal (6 weeks) **Country:**Norway
Participants	**N=**56 (cases = [1], control = [2]) **Mean age (SD):** 30 **Ethnicity: N/R**
Study design	Cross-sectional case-control

Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**PRIME-MD, DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	
Notes	[1]EPDS score>10 [2]EPDS score<10

1.1.21 HARRIS1989

Study ID	HaRRIS1989
Bibliographic reference	Harris B, Huckle P, Thomas R, Johns S, Fung H. The use of rating scales to identify post-natal depression. British Journal of Psychiatry. 1989;154:813-7
Clinical features and settings	**Recruitment:** antenatal booking clinic **Timing:** Postnatal **Country:** UK
Participants	**N=**126 **Mean age : 25**
Study design	Cross-sectional Cohort
Target condition	Major epression
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-III **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Clinician
Index cut-off	12/13
Limitations	
Source of funding	NR
Notes	

1.1.22 EKEROMA2012

Study ID	**EKEROMA2012**
Bibliographic reference	Ekeroma AJ, Ikenasio-Thorpe B, Weeks S, Kokaua J, Puniani K, Stone P et al. Validation of the Edinburgh Postnatal Depression Scale (EPDS) as a screening tool for postnatal depression in Samoan and Tongan women living in New Zealand. New Zealand Medical Journal. 2012;125(1355):41-50.
Clinical features and settings	**Recruitment:** Referral hospital **Timing:** Postnatal (4-7 weeks) **Country:**Tonga and Samoa
Participants	**N=**query (cases = [1], control = [2])

	Mean age (SD): 30 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**WHO-CIDI v3 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.23 FELICE2006

Study ID	FELICE2006
Bibliographic reference	Felice E, Saliba J, Grech V, Cox J. Validation of the Maltese version of the Edinburgh Postnatal Depression Scale. Archives of Women's Mental Health. 2006;9(2):75-80
Clinical features and settings	**Recruitment:** Antenatal clinic **Timing:** Pregnancy and Postnatal **Country:**Malta
Participants	**N=**233 (cases = [1], control = [2]) **Mean age:** 27 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**CIS-R ICD-10 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	

1.1.24 FERNANDES2011

Study ID	FERNANDES2011
Bibliographic reference	Fernandes MC, Srinivasan K, Stein AL, Menezes G, Sumithra R, Ramchandani PG. Assessing prenatal depression in the rural developing world: a comparison of two screening measures. Archives of Womens Mental Health. 2011;14:209-16.

Clinical features and settings	**Recruitment:** Prenatal clinic **Timing:** Pregnancy (third trimester) **Country:**India
Participants	**N=**194 (cases = [1], control = [2]) **Mean age:** 22 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Combined major and minor depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10, Kessler-10 **2.Reference Standard:**MINIPlus [DSM-IV TR, ICD-10] **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** ADD
Index cut-off	Multiple
Limitations	
Source of funding	ADD
Notes	[1]Excluded history of schizophrenia or other psychotic illness.

1.1.25 FLYNN2011

Study ID	FLYNN2011
Bibliographic reference	Flynn HA, Sexton M, Ratliff S, Porter K, Zivin K. Comparative performance of the Edinburgh Postnatal Depression Scale and the Patient Health Questionnaire-9 in pregnant and postpartum women seeking psychiatric services. Psychiatry Research. 2011;187(1-2):130-4.
Clinical features and settings	**Recruitment:** Access psychiatry services **Timing:** Pregnancy+Postnatal (third trimester) **Country:**US
Participants	**N=**185 (cases = [1], control = [2]) **Mean age:** 30 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10, PHQ **2.Reference Standard:**DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Clinican
Index cut-off	Multiple
Limitations	Selection based on seeking psychiatric services.
Source of funding	ADD
Notes	

1.1.26 GARCIA-ESTEVE2003

Study ID	GARCIA-ESTEVE2003
Bibliographic reference	Garcia-Esteve L, Ascaso C, Ojuel J, Navarro P. Validation of the Edinburgh Postnatal Depression Scale (EPDS) in Spanish mothers. Journal of Affective Disorders. 2003;75:71-6.
Clinical features and settings	**Recruitment:** Postnatal checkup **Timing:** Pregnancy+Postnatal (6 weeks) **Country:** Spain
Participants	**N=**334 (cases = [1], control = [2]) **Mean age (SD):** 30 **Ethnicity: N/R**
Study design	Cross-sectional cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS-10 **2.Reference Standard:**DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Clinican
Index cut-off	Multiple
Limitations	Selection based on seeking psychiatric services.

Source of funding	ADD
Notes	1 2

1.1.27 GAUSIA2007

Study ID	GAUSIA2007
Bibliographic reference	Gausia K, Fisher C, AlgincS, OosthuizendJ. Validation of the Bangla version of the Edinburgh Postnatal Depression Scale for a Bangladeshi sample.Journal of Reproductive and Infant Psychology. 2007;25(4):308-15.
Clinical features and settings	**Recruitment:** Government immunization clinic **Timing:** Postnatal **Country:** Bangaldesh
Participants	**N=**126 **Mean age:** 26 **Language:** Bengali
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Research assistant **2.Reference Standard:** Psychiatrist
Prevalence	9%
Index cut-off	Multiple
Limitations	
Source of funding	International Centre for Diarrhoeal Disease Research, Bangladesh: Centre for Health and Population Research and the Department for International Development (DFID).
Notes	

1.1.28 GHUBASH1997

Study ID	**GHUBASH1997**
Bibliographic reference	Ghubash R, Abou-Saleh MT, Daradkeh TK.The validity of the Arabic Edinburgh postnatal depression scale.Social Psychiatry and Psychiatric Epidemiology. 1997;32(8):474-6.
Clinical features and settings	**Recruitment:** New Dubai Hospital in Dubai **Timing:** Postnatal **Country:** United Arab Emirates
Participants	**N =** 95 **Mean age: 29** **Ethnicity:** Arab **Language:** Arabic
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-10 **Assessors** **1.Instrument:** NR **2.Reference Standard: NR**
Prevalence	14%
Index cut-off	10 and 12
Limitations	
Source of funding	NR
Notes	

1.1.29GUEDENEY1998

Study ID	**GUEDENEY1998**
Bibliographic reference	Gjerdincjen D, Crow S, McGovern P, Miner M, Center B. Postpartum depression screening at well-child visits: Validity of a 2-question screen and the PHQ-9. Annals of Family Medicine. 2009;7:63-70.
Clinical features and settings	**Recruitment:** Recruited by nurses of the Protection Matemelle et Infantile (PMI) in Paris **Timing:** Postnatal **Country:** France
Participants	**N =** 87 (cases = 47, control = 40) **Mean age:** 30 **Ethnicity:** NR **Language:** French
Study design	Case-control
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** PHQ **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report

	2.Reference Standard: Study authors
Prevalence	52%
Index cut-off	Optimal
Limitations	
Source of funding	NR
Notes	

1.1.30 GJERDINCJEN2009

Study ID	GJERDINCJEN2009
Bibliographic reference	Gjerdincjen D, Crow S, McGovern P, Miner M, Center B. Postpartum depression screening at well-child visits: Validity of a 2-question screen and the PHQ-9. Annals of Family Medicine. 2009;7:63-70
Clinical features and settings	**Recruitment:** metropolitan area clinics **Timing:** Postnatal **Country:** US
Participants	**N =** 506 **Age:** 29 **Language:** English
Study design	Cohort
Target condition	Major depression
Index and comparator tests	**1.Instrument:** PHQ (2, 9 version), whooley questions **2.Reference Standard:** DSM-IV (SCID) **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Clinician
Prevalence	9%
Index cut-off	9/10
Limitations	
Source of funding	
Notes	Validity test results are taken from those over the entire study period (0-9 m PN) rather than in the initial visit 0-1 month as it is difficult to distinguish between PN depression awhen early postpartum period when "the blues" are common. No risk factors present

1.1.31 JADRESIC1995

Study ID	**JADRESIC1995**
Bibliographic reference	Jadresic E. Validation of the Edinburgh postnatal depression scale (EPDS) in Chilean postpartum women. Journal of Psychosomatic Obstetrics and Gynaecology. 1995;16:187-191.
Clinical features and settings	**Recruitment:** Antenatal clinic university hospital **Timing:** Postnatal **Country:** Chile
Participants	**N=**108 **Mean age (SD):** 28 **Ethnicity: NR** **Language:** Spanish
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator	**1.Instrument:** EPDS

tests	**2.Reference Standard:** Research diagnostic criteria **Assessors** **1.Instrument:** **2.Reference Standard:**
Prevalence	10%
Index cut-off	Mulitple
Limitations	
Source of funding	NR
Notes	

1.1.32 KADIR2005

Study ID	**KADIR2005**
Bibliographic reference	Kadir AA, Nordin R, Shaiful BI, Mohd JY, Wan Mohd RWM. Validation of the Malay version of Edinburgh Postnatal Depression Scale for postnatal women in Kelantan, Malaysia. International Medical Journal. 2005;12:105-109.
Clinical features and settings	**Recruitment:** Health Centre for routine postpartum examination **Timing:** Postnatal **Country:** Malaysia
Participants	**N =** 52 **Mean age:** NR **Ethnicity:** NR **Language:** Malay
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** CIS **Assessors** **1.Instrument:** NR **2.Reference Standard:** NR
Prevalence	NR
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.33 LAU2010

Study ID	**LAU2010**
Bibliographic reference	Lau Y, Wang Y, Yin L, Chan KS, Guo X. Validation of the Mainland Chinese version of the Edinburgh Postnatal Depression Scale in Chengdu mothers. International Journal of Nursing Studies. 2010;47:1139-1151.
Clinical features and settings	**Recruitment:** Outpatients clinics in four regional hospitals **Timing:** Postnatal **Country:** China
Participants	**N =** 342 **Mean age:** NR **Ethnicity:** NR **Language:** Chinese
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** CIS **Assessors** **1.Instrument:** NR **2.Reference Standard:** NR
Prevalence	NR
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.34 LEE1998

Study ID	**LEE1998**
Bibliographic reference	Lee DT, Yip SK, Chiu HF, Leung TY, Chan KP, Chau IO, et al. Detecting postnatal depression in Chinese women. Validation of the Chinese version of the Edinburgh Postnatal Depression Scale.British Journal of Psychiatry. 1998;172:433-7
Clinical features and settings	**Recruitment:** University-affiliated general hospital **Timing: Postnatal** **Country: Hong Kong**
Participants	**N=**145 **Mean age (SD): 29** **Ethnicity: NR** **Language: Chinese**
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Prevalence	12%
Index cut-off	Multiple
Limitations	
Source of funding	Hospital Services Research Fund
Notes	

1.1.35 LEONARDOU2009

Study ID	**LEONARDOU2009**
Bibliographic reference	Leonardou A, Zervasa YM, Papageorgioua CC, Marksb MN, TsartsaraaEC, Antsaklisc A,et al. Validation of the Edinburgh Postnatal Depression Scale and prevalence of postnatal depression at two months postpartum in a sample of Greek mothers. Journal of Reproductive and Infant Psychology. 2009;27:28-39
Clinical features and settings	**Recruitment:** Private maternity hospital **Timing: Postnatal** **Country: Greece**
Participants	**N=**81 **Mean age: 32** **Ethnicity: NR** **Language: Greek**
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-III-R **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Trained researcher
Prevalence	12%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.36 LEVERTON2000

Study ID	**LEVERTON2000**
Bibliographic reference	Leverton TJ, Elliott SA. Is the EPDS a magic wand? A comparison of the Edinburgh Postnatal Depression Scale and health visitor report as predictors of diagnosis on the present state examination. Journal of Reproductive and Infant Psychology. 2000;18:279-96
Clinical features and settings	**Recruitment:** Antenatal clinic **Timing: Postnatal** **Country: UK**
Participants	**N=199** **Mean age (SD): NR** **Ethnicity: NR** **Language: English**
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-8 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrists
Prevalence	5%
Index cut-off	9/10
Limitations	
Source of funding	Gatsby Charitable Foundation
Notes	

1.1.37MANN2012

Study ID	**MANN2012**
Bibliographic reference	Mann R, Adamson J, Gilbody SM. Diagnostic accuracy of case-finding questions to identify perinatal depression. Canadian Medical Association Journal. 2012:184;e424-430
Clinical features and settings	**Recruitment:** maternity unit in a UK National Health Service general hospital **Timing:** Pregnancy and postnatal **Country:** UK
Participants	**N =** 152 **Mean age:** 27 **Language:** English
Study design	Cohort
Target condition	Major Depression
Index and comparator tests	**1.Instrument:** Whooley questions **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:**
Prevalence	
Index cut-off	N/A
Limitations	
Source of funding	NR
Notes	

1.1.38 MAHMUD2003

Study ID	MAHMUD2003
Bibliographic reference	Mahmud WM, Awang A, Mohamed MN. Revalidation of the Malay Version of the Edinburgh Postnatal Depression Scale (EPDS) Among Malay Postpartum Women Attending the Bakar Bata Health Center in AlorSetar, Kedah, North West Of Peninsular Malaysia. The Malaysian Journal of Medical Sciences. 2003;10:71-5
Clinical features and settings	**Recruitment:** Health Center **Timing:** Postnatal **Country:** Malaysia
Participants	**N =** 64 **Mean age: 29** **Ethnicity: NR** **Language:** Malay
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-10 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Study authors
Prevalence	14%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.39 MATTHEY2008

Study ID	**MATTHEY2008**
Bibliographic reference	Matthey S. Using the Edinburgh Postnatal Depression Scale to screen for anxiety disorders. Depression and Anxiety. 2008;25:926-31
Clinical features and settings	**Recruitment:** Antenatal classes at a public hospital **Timing:** Postnatal **Country:** Australia
Participants	**N =** 238 **Mean age:** 27 **Ethnicity:** NR **Language:** English
Study design	Cohort
Target condition	Anxiety disorder
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-III-R **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Trained researchers
Prevalence	7.6%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.40 MAZHARI2007

Study ID	**MAZHARI2007**
Bibliographic reference	Mazhari S, Nakhaee N. Validation of the Edinburgh Postnatal Depression Scale in an Iranian sample. Archives of Women's Mental Health. 2007;10:293-7.
Clinical features and settings	**Recruitment:** Mothers attending infant's vaccination program **Timing: Postnatal** **Country: Iran**
Participants	**N=**200 (cases = 100, control = 100) **Mean age:** 26 **Ethnicity: NR** **Language: Farsi**
Study design	Case-control
Target condition	Major depression and combined major and minor depression
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Research assistant **2.Reference Standard:** Psychiatrist
Prevalence	20%
Index cut-off	Multiple
Limitations	
Source of funding	Neuroscience Research Centre, Kerman University of Medical Sciences.
Notes	

1.1.41 MILGROM2005A

Study ID	**MILGROM2005A**
Bibliographic reference	Milgrom J, Ericksen J, Negri L, Gemmill AW. Screening for postnatal depression in routine primary care: properties of the Edinburgh Postnatal Depression Scale in an Australian sample. The Australian and New Zealand Journal of Psychiatry. 2005a. 39:833-9
Clinical features and settings	**Recruitment:** Maternal and child health centres **Timing:** Postnatal **Country:** Australia
Participants	**N=**344 **Mean age (SD):** 30 **Ethnicity:** NR **Language:** English
Study design	Cohort
Target condition	Major depression and combined major and minor depression
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-rated **2.Reference Standard:** Study authors
Prevalence	20%
Index cut-off	Multiple
Limitations	
Source of funding	Research & Development Grants Advisory Committee/NHMRC Public Health and Austin Hospital Medical Research Foundation
Notes	

1.1.42 MURRAY1990B

Study ID	**MURRAY1990B**
Bibliographic reference	Murray D, Cox JL. Screening for depression during pregnancy with the Edinburgh Depression Scale (EDDS).Journal of Reproductive and Infant Psychology. 1990;8:2,99-107
Clinical features and settings	**Recruitment:** Antenatal clinic of large maternity hospital **Timing:** Pregnancy **Country:** UK
Participants	**N=**100 **Mean age (SD):** NR **Ethnicity:** NR **Language:** English
Study design	Cohort
Target condition	Major depression and combined major and minor depression

Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** RDC **Assessors** **1.Instrument:** Self-rated **2.Reference Standard:** Psychiatrist/psychologist
Prevalence	6%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.43 MUZIK2000

Study ID	**MUZIK2000**
Bibliographic reference	Muzik M, Klier CM, Rosenblum KL, Holzinger A, Umek W, Katschnig H. Are commonly used self-report inventories suitable for screening postpartum depression and anxiety disorders? Acta Psychiatrica Scandinavica. 2000;102:71-3
Clinical features and settings	**Recruitment:** Drawn from a larger epidemiological study of postpartum depression in Austria **Timing:** Postnatal **Country:** Austria
Participants	**N=**50 **Mean age (SD):** 28 **Ethnicity:** NR **Language:** German
Study design	Cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-III **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Prevalence	18%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.44 PHILLIPS2009

Study ID	**PHILLIPS2009**
Bibliographic reference	Phillips J, Charles M, Sharpe L, Matthey S. Validation of the subscales of the Edinburgh Postnatal Depression Scale in a sample of women with unsettled infants.Journal of Affective Disorders. 2009;118:101-12

Clinical features and settings	**Recruitment:** Parent- infant unit **Timing:** Postnatal **Country:** Australia
Participants	**N=**166 **Mean age:** 32 **Ethnicity:** NR **Language:** English
Study design	Cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychologist
Prevalence	25%
Index cut-off	Multiple
Limitations	
Source of funding	National Health and Medical Research Council of Australia
Notes	

1.1.45 PITANUPONG2007

Study ID	**PITANUPONG2007**
Bibliographic reference	Pitanupong J, Liabsuetrakul T, Vittayanont A. Validation of the Thai Edinburgh Postnatal Depression Scale for screening postpartum depression. Psychiatry Research. 2007;149:253-9
Clinical features and settings	**Recruitment:** University hospital in South of Thailand **Timing:** Postnatal **Country:** Thailand
Participants	**N=**615 **Mean age (SD):** 28 **Ethnicity:** NR **Language:** Thai
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatrist
Prevalence	11%
Index cut-off	Multiple
Limitations	
Source of funding	Faculty of Medicine, Prince of Songkla University

Notes	

1.1.46 REGMI2002

Study ID	**REGMI2002**
Bibliographic reference	Regmi S, Sligl W, Carter D, Grut W, Seear M. A controlled study of postpartum depression among Nepalese women: validation of the Edinburgh Postpartum Depression Scale in Kathmandu. Tropical Medicine and International Health. 2002;7:378-82
Clinical features and settings	**Recruitment:** Public postnatal clinic **Timing:** Postnatal **Country:** Nepal
Participants	**N =** 140 (cases=100; controls = 40) **Mean age (SD):** NR **Ethnicity:** NR **Language:** Nepali
Study design	Case-control
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** NR **2.Reference Standard:** NR
Prevalence	12%
Index cut-off	12/13
Limitations	
Source of funding	University of British Columbia
Notes	

1.1.47 RUBBERTSSON2011

Study ID	**RUBBERTSSON2011**
Bibliographic reference	Rubertsson C, Börjesson K, Berglund A, Josefsson A, Sydsjö G. The Swedish validation of Edinburgh Postnatal Depression Scale (EPDS) during pregnancy. Nordic Journal of Psychiatry. 2011;65:414-18
Clinical features and settings	**Recruitment:** Antenatal care clinics **Timing:** Pregnancy **Country:** Sweden
Participants	**N =** 121 **Mean age (SD):** 30 **Ethnicity:** NR **Language:** Swedish
Study design	Cohort
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** NR
Prevalence	7%
Index cut-off	Multiple
Limitations	
Source of funding	Söderström Köniska stiftelsen
Notes	

1.1.48 SANTOS2007

Study ID	**SANTOS2007**
Bibliographic reference	Santos IS, MatijasevichI A, Franck TavaresI B,Barros AJD,PicininiBotelhoI I, LapollC, et al. Validation of the Edinburgh Postnatal Depression Scale (EPDS) in a sample of mothers from the 2004 Pelotas Birth Cohort Study. Cadernos de SaudePublica. 2007;23(11):2577-88
Clinical features and settings	**Recruitment:** Children born in the city's five hospitals **Timing:** Postnatal **Country:** Brazil
Participants	**N =** 378 (cases=219, controls = 159) **Mean age (SD):** NR **Ethnicity:** NR **Language:** Portuguese
Study design	Case-control
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-10 **Assessors**

	1.Instrument: Trained interviewer **2.Reference Standard:** Trained mental health professional
Prevalence	28%
Index cut-off	Multiple
Limitations	
Source of funding	World Health Organization (HQ/04/072979), the Brazilian National Research Council (CNPq grant no.476727/2003-0), and the Children's Mission (Pastoral da Criança).
Notes	

1.1.49 SIDEBOTTOM2012

Study ID	SIDEBOTTOM2012
Bibliographic reference	Sidebottom AC, Harrison PA, Godecker A, Kim H. Validation of the Patient Health Questionnaire (PHQ)-9 for prenatal depression screening. Archives of Women's Mental Health. 2012;15:367-74
Clinical features and settings	**Recruitment:** community health care centers **Timing:** Pregnancy **Country:** US
Participants	**N =** 745 **Mean age:** 23 **Language:** English
Study design	Cohort
Target condition	Major depression and combined major and minor depression
Index and comparator tests	**1.Instrument:** PHQ-9 **2.Reference Standard:** DSM-IV (SCID) **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Trained professional
Prevalence	Major depression (4%), combined major and minor depression (10%)
Index cut-off	9/10
Limitations	
Source of funding	
Notes	

1.1.50 SMITH2010

Study ID	SMITH2010
Bibliographic reference	Smith MV, Gotman N, Lin H, Yonkers KA. Do the PHQ-8 and the PHQ-2 accurately screen for depressive disorders in a sample of pregnant women? General Hospital Psychiatry. 2010;32(5):544-8
Clinical features and settings	**Recruitment:** Pregnant women attending prenatal care **Timing:** Pregnancy **Country:** US
Participants	**N =** 218

	Mean age: 29 **Language:** English
Study design	Case-control[1]
Target condition	Major depression
Index and comparator tests	**1.Instrument:** PHQ-2 **2.Reference Standard:** CIDI **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Trained professional
Prevalence	6%
Index cut-off	PHQ-2: 3/4 PHQ-8: 9/10
Limitations	
Source of funding	
Notes	[1] Women who endorsed depressed mood or treatment + also randomly selected one out of every three women who were not taking antidepressants and were neither diagnosed with nor treated for a depressive disorder in the last 5 years

1.1.51 SPIES2010

Study ID	**SPIES2010**
Bibliographic reference	Spies G, Stein DJ, Roos A, Faure SC, Mostert J, Seedat S. Validity of the Kessler 10 (K-10) in detecting DSM-IV defined mood and anxiety disorders among pregnant women. Archives of Women's Mental Health. 2010; 69-74: 69-74
Clinical features and settings	**Recruitment:** midwife obstetric units **Timing:** Pregnancy **Country:** South Africa
Participants	**N =** 129 **Mean age:** NR **Language:** Afrikaans
Study design	Cohort
Target condition	Anxiety disorders
Index and comparator tests	**1.Instrument:** Kessler-10 **2.Reference Standard:** SCID DSM-IV **Assessors** **1.Instrument:** Seld-report **2.Reference Standard:** Clinician
Prevalence	17%
Index cut-off	5/6
Limitations	
Source of funding	NR
Notes	

1.1.52 TANDON2012

Study ID	**TANDON2012**
Bibliographic reference	Tandon SD, Cluxton-Keller F, Leis J, Le HN, Perry DF.A comparison of three screening tools to identify perinatal depression among low-income African American women. Journal of Affective Disorders. 2012;136:155-62
Clinical features and settings	**Recruitment:** Baltimore City home visitation programs **Timing:** Pregnancy/Postnatal **Country:** USA
Participants	**N =** 92 (cases=NR, controls = NR) **Mean age (SD):** 24 **Ethnicity:** African american (100%) **Language:** English
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Clinical social worker **2.Reference Standard:** Clinical social worker
Prevalence	34%
Index cut-off	Multiple
Limitations	
Source of funding	Thomas Wilson Sanitarium
Notes	

1.1.53 TENG2005

Study ID	**TENG2005**
Bibliographic reference	Teng HW, Hsu CS, Shih SM, Lu ML, Pan JJ, Shen WW. Screening postpartum depression with the Taiwanese version of the Edinburgh Postnatal Depression Scale. Comprehensive Psychiatry. 2005;46:261-5
Clinical features and settings	**Recruitment:** Maternity wards **Timing:** Postnatal **Country:** Taiwan
Participants	**N =** 203 **Mean age:** 29 **Ethnicity:** NR **Language:** Taiwanese
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Psychiatric specialist
Prevalence	12%

Index cut-off	Multiple
Limitations	
Source of funding	National Science Council, Taiwan
Notes	

1.1.54 THIAGAYSON2013

Study ID	**THIAGAYSON2013**
Bibliographic reference	Thiagayson P, Krishnaswamy G, Lim ML, Sung SC, Haley CL, Fung DS et al. Depression and anxiety in Singaporean high-risk pregnancies – prevalence and screening. General Hospital Psychiatry. 2013;35:112-6.
Clinical features and settings	**Recruitment:** Maternity wards **Timing:** Postnatal **Country:** Singapore
Participants	**N =** 200 **Mean age:** 31 **Ethnicity:** Chinese (40%), Malay (37.5%), Indian (14%) **Language:** NR
Study design	Cohort
Target condition	Major depression and combined major and minor depression
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Principal investigator
Prevalence	18%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.55 TOREKI2013

Study ID	**TOREKI2013**
Bibliographic reference	Toreki A, Andó B, Keresztúri A, Sikovanyecz J, Dudas RB, Janka Z. The Edinburgh Postnatal Depression Scale: translation and antepartum validation for a Hungarian sample. Midwifery. 2013;29:308-15
Clinical features and settings	**Recruitment:** Routine check-up at 12 weeks antepartum **Timing:** Pregnancy **Country:** Hungary
Participants	**N =** 219 **Mean age:** 30 **Ethnicity:** NR **Language:** Hungarian
Study design	Cohort

Target condition	Major depression and combined major and minor depression
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Clinical psychologist
Prevalence	3%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.56 TRAN2011

Study ID	**TRAN2011**
Bibliographic reference	Tran TD, Tran T, La B, Lee D, Rosenthal D, Fisher J. Screening for common perinatal mental disorders in women in the north of Vietnam: a comparison of three psychometric instruments. Asian Journal of Psychiatry. 2011;4:S83-S84
Clinical features and settings	**Recruitment:**Mmothers registered for pregnancy or newborn health care at the commune health station **Timing:** Pregnancy/Postnatal **Country:** Vietnam
Participants	**N =** 364 **Mean age (SD):** NR **Ethnicity:** NR **Language:** Vietnamese
Study design	Cohort
Target condition	Common mental health disorder
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-IV **Assessors** **1.Instrument:** Health research worker **2.Reference Standard:** Psychiatrist
Prevalence	3%
Index cut-off	Multiple
Limitations	
Source of funding	Myer Foundation
Notes	

1.1.57 UWAKWE2003

Study ID	**UWAKWE2003**
Bibliographic reference	Uwakwe R, Okonkwo JE. Affective (depressive) morbidity in puerperal Nigerian women: validation of the Edinburgh postnatal depression scale. ActaPsychiatricaScandinavica. 2003;107:251-9
Clinical features and settings	**Recruitment:** Wards and postnatal clinics **Timing:** Postnatal **Country:** Nigeria
Participants	**N =** 225 **Mean age (SD):** 29 **Ethnicity:** NR **Language:** Igbo
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-10 **Assessors**

	1.Instrument: Trained resident doctors **2.Reference Standard:** Psychiatrist and experiences psychiatric nurse
Prevalence	11%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.58WERRETT2006

Study ID	**WERRETT2006**
Bibliographic reference	Werrett J, Clifford C. Validation of the Punjabi version of the Edinburgh postnatal depression scale (EPDS). International Journal of Nursing Studies. 2006;43(2):227-36
Clinical features and settings	**Recruitment:** Healthcare trusts **Timing:** Postnatal **Country:** UK
Participants	**N =** 23 **Mean age:** 29 **Ethnicity:** Asian **Language:** English and Punjabi
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** ICD-10 **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** Researcher
Prevalence	3%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.59WICKBERG1996

Study ID	**WICKBERG1996**
Bibliographic reference	Wickberg B, Hwang CP. The Edinburgh Postnatal Depression Scale: validation on a Swedish community sample. ActaPsychiatricaScandinavica. 1996;94:181-4
Clinical features and settings	**Recruitment:** Child health clinics **Timing:** Postnatal **Country:** Sweden
Participants	**N =** 41 (cases=20, controls=21) **Mean age:** 28 **Ethnicity:** NR **Language:** Swedish
Study design	Case-control
Target condition	Major depression (only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** DSM-III-R **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** NR

Prevalence	44%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.1.60 YOSHIDA2001

Study ID	**YOSHIDA2001**
Bibliographic reference	Yoshida K, Yamashita H, Ueda M, Tashiro N. Postnatal depression in Japanese mothers and the reconsideration of 'Satogaeribunben'. Pediatrics International. 2001;43:189-93
Clinical features and settings	**Recruitment:** Antenatal classes and advertisement **Timing:** Postnatal **Country:** UK/Japan
Participants	**N =** 98 **Mean age:** NR **Ethnicity:** NR **Language:** Japanese
Study design	Cohort
Target condition	Major and minor depression (combined only)
Index and comparator tests	**1.Instrument:** EPDS **2.Reference Standard:** RDC **Assessors** **1.Instrument:** Self-report **2.Reference Standard:** NR
Prevalence	17%
Index cut-off	Multiple
Limitations	
Source of funding	NR
Notes	

1.2 CASE IDENTIFICATION – EXCLUDED STUDIES

Study	Reason for exclusion
Abiodun AO. A validity study of the Hospital Anxiety and Depression Scale in general hospital units and a community sample in Nigeria. British Journal of Psychiatry.1994;165:669-672.	Data could not be extracted (Focus of the study not to validate in the perinatal period. Provides disaggregated data for 'antenatal clincs' however no other information is provided about the population, timing of administration, whether to used to detect anxiety or depression)
Abiodun OA, Adetoro OO, Ogunbode OO. Psychiatric morbidity in a pregnant population in Nigeria. General Hospital Psychiatry. 993;15: 125-128.	Over 12 items
Allison KC, Wenzel A, Kleiman K, Sarwer DB. Development of a brief measure of postpartum distress. Journal of Women's Health.201120;617-623.	No gold standard
Areias ME, Kumar R, Barros H, Figueiredo E. Comparative incidence of depression in women and men, during pregnancy and after childbirth. Validation of the Edinburgh Postnatal Depression Scale in Portuguese mothers. British Journal of Psychiatry. 1996:169;30-5	Data could not be extracted
Austin MP, Hadzi-Pavlovic D, Priest SR, Reilly N, Wilhelm K, Saint K. Depressive and anxiety disorders in the postpartum period: how prevalent are they and can we improve their detection? Archives Womens Mental Health. 2010;13:395-401	No relevant outcomes
Austin MP, Hadzi-Pavlovic D, Saint K, Parker G. Antenatal screening for the prediction of postnatal depression: Validation of a psychosocial Pregnancy Risk Questionnaire. Acta Psychiatrica Scandinavica. 2005;112: 310-317	Over 12 items
Beck CT, Gable RK Postpartum depression screening scale: Spanish version. Nursing Research. 2003; 52:296-306	Over 12 items
Bennett IM, Coco A, Coyne JC, Mitchell AJ, Nicholson J, Johnson E, et al. Efficiency of a two-item pre-screen to reduce the burden of depression screening in pregnancy and postpartum: An IMPLICIT network study. Journal of the American Board of Family Medicine. 2008;21: 317-32	No gold standard
Bermejo Calzada A, Lopez Velasco N, Abehsera Davo D, Arrieta Breton S, Gonzalez Gonzalez A. Edinburgh's test as screening of postpartum depression. Journal of Maternal-Fetal and Neonatal Medicine. 2010; 23: 379-380.	No access to paper
Birmingham MC, Chou KJ, Crain EF. Screening for postpartum depression in a pediatric emergency department. Pediatric Emergency Care. 2011;27: 795-800.	No gold standard
Bunevicius A, Kusminskas L, Pop VJ, Pedersen C. Bunevicius, R. Screening for depression during pregnancy. European Neuropsychopharmacology. 2009;19: S364-S365.	Abstract
Chae SY, Chae MH, Tyndall A, Ramirez MR, Winter RO. Can we effectively use the two-item PHQ-2 to screen for postpartum depression?. Family medicine. 2012;44:698-703.	No gold standard

Cooper PJ, Murray L, Hooper R, West A. The development and validation of a predictive index for postpartum depression. Psychological medicine. 1996; 26:627-634.	Over 12 items
Cox JL, Chapman G, Murray D, Jones P. Validation of the Edinburgh postnatal depression scale (EPDS) in non- postnatal women. Journal of Affective Disorders;199639:185-189	Not a perinatal population (aim of paper to validate in non-postnatal women)
Crotty F, Sheehan J. Prevalence and detection of postnatal depression in an Irish community sample. 2004. Irish Journal of Psychological Medicine;21: 117-121	Data could not be extracted (Sensitivity and specificity could not be extracted)
Cutler CB, Legano LA, Dreyer BP, Fierman AH, Berkule SB, Lusskin SI. Screening for maternal depression in a low education population using a two item questionnaire. Archives of Women's Mental Health. 2007;10: 277-283.	No gold standard
Dennis CL, Boyce P. Further psychometric testing of a brief personality scale to measure vulnerability to postpartum depression. Journal of Psychosomatic Obstetrics and Gynecology. 2004;25: 305-311	No gold standard
Dennis CL. Can we identify mothers at risk for postpartum depression in the immediate postpartum period using the Edinburgh Postnatal Depression Scale?. Journal of Affective Disorders. 2004;78: 163-169	No gold standard
Des Rivieres-Pigeon C, Seguin L, Brodeur JM, Perreault M, Boyer G, Colin C. The Edinburgh Postnatal Depression Scale: Validity for Quebec women of low socioeconomic status. Canadian Journal of Community Mental Health. 2002;19: 201-214	No relevant outcomes
Figueiredo FP, Balarini FB, Silva APC, Cavalli RC, Silva AA, Bettiol H. EPDS by telephone: What cutoff point use." European Psychiatry. 2012;27.	Abstract
Glaze R, Cox JL. Validation of a computerised version of the 10-item (self-rating) Edinburgh Postnatal Depression scale. Journal of Affective Disorders. 1991;22: 73-77	No relevant outcomes
Gunning MD, Denison FC, Stockley CJ, Ho SP, Sandhu HK, Reynolds RM.Assessing maternal anxiety in pregnancy with the State-Trait Anxiety Inventory (STAI): Issues of validity, location and participation. Journal of Reproductive and Infant Psychology. 2010;28: 266-273.	Over 12 items
Hamdan A, Tamim H. Psychosocial risk and protective factors for postpartum depression in the United Arab Emirates. Archives of Women's Mental Health. 2011;14: 125-133.	No relevant outcomes
Hanlon C, Medhin G, Alem A, Araya M, Abdulahi A, Hughes M, et al. Detecting perinatal common mental disorders in Ethiopia: Validation of the self-reporting questionnaire and Edinburgh Postnatal Depression Scale. Detecting perinatal common mental disorders in Ethiopia: Validation of the self-reporting questionnaire and Edinburgh Postnatal Depression Scale. 2008:108;251-262	Data could not be extracted
Hanusa BH, Scholle SH, Haskett RF, Spadaro K, Wisner KL. Screening for depression in the postpartum period: A comparison of three instruments. Journal of Women's Health. 2008:17;585-596	Data could not be extracted
Heh SS. Validation of the Chinese version of the Edinburgh Postnatal Depression Scale: detecting postnatal depression in Taiwanese women. Hu li yan jiu. Nursing research. 2001; 9:105-113	No gold standard
Hundley V, Gurney E, Graham W, Rennie AM. Can anxiety in pregnant women be measured using the State-Trait Anxiety Inventory. Midwifery. 1998;14: 118-121.	Over 12 items
Ip WY, Martin C. The factor structure of the Chinese version of the Edinburgh Postnatal Depression Scale (EPDS). Journal of Reproductive and	No relevant outcomes

Infant Psychology. 2007; 25: 83-86	
Jardri R, Pelta J, Maro, M, Delion P, Codaccioni X, Goudemand M. Predictive validation study of the Edinburgh Postnatal Depression Scale in the first week after delivery and risk analysis for postnatal depression. Journal of Affective Disorders. 2006;93:1-3	Data could not be extracted
Ji S, Long Q, Newport JD, Na H, Knight B. Zach EB. Validity of depression rating scales during pregnancy and the postpartum period: Impact of trimester and parity. Journal of Psychiatric Research. 2006:45; 213-219	Data could not be extracted
Kabir K, Sheeder J, Kelly LS. Identifying postpartum depression: are 3 questions as good as 10? Pediatrics; 2998;122: e696-702.	Abstract
Karmaliani R, Bann CM, Pirani F, Akhtar S, Bender RH, Goldenberg RL. Diagnostic validity of two instruments for assessing anxiety and depression among pregnant women in Hyderabad, Pakistan. Health Care for Women International. 2007;28: 556-572.	Over 12 items
Kheirabadi GR, Maracy MR, Akbaripour S, Masaeli N. Psychometric properties and diagnostic accuracy of the Edinburgh Postnatal Depression Scale in a sample of Iranian women. Iranian Journal of Medical Sciences. 2012;37: 32-38	No gold standard
Kitamura T, Shima S, Sugawara M, Toda MA. Temporal variation of validity of self-rating questionnaires: Repeated use of the general health questionnaire and Zung's self-rating depression scale among women during antenatal and postnatal periods. Acta Psychiatrica Scandinavica. 1994;90: 446-450.	Over 12 items
Lagerberg D, Magnusson M, Sundelin C. Drawing the line in the Edinburgh Postnatal Depression Scale (EPDS): A vital decision. International Journal of Adolescent Medicine and Health. 2011;23: 27-32.	cut off point not appropriate 11/12
Lawrie TA, Hofmeyr GJ, De Jager M, Berk M. Validation of the Edinburgh Postnatal Depression Scale on a cohort of South African women. South African Medical Journal. 1998:88;1340-1344	Data could not be extracted
Logsdon MC, Myers JA. Comparative performance of two depression screening instruments in adolescent mothers. Journal of women's health. 2010:19; 1123-1128	Adolescent population not appropriate
Martin CR, Jomeen J. (Is the 12-item General Health Questionnaire (GHQ-12) confounded by scoring method during pregnancy and following birth?" Journal of Reproductive and Infant Psychology. 2003; 21:267-278	No relevant outcomes
Martinez J, Garcia-Leon A, Olalla L. Construction and validation of an instrument to evaluate the anxiety in high risk pregnant women. Revista Iberoamericana de Diagnostico y Evaluacion Psicologica. 2003;15: 93-105	Not in English
Matthey S, Barnett B, Kavanagh DJ, Howie P. Validation of the Edinburgh Postnatal Depression Scale for men, and comparison of item endorsement with their partners. Journal of Affective Disorders. 2001;64: 175-184.	Data could not be extracted (Aim of the paper not to validate in postnatal women. Sensitivity and specificity measures not diaggregated for depression and anxiety)
Matthey S, Phillips J, White T, Glossop P, Hopper U, Panasetis P, Petridis A, Larkin M, Barnett B (2004) Routine psychosocial assessment of women in the antenatal period: frequency of risk factors and implications for clinical services. Arch Womens Ment Health 7:223–229	No relevant outcomes
Montazeri A,Torkan B, Omidvari SA. The Edinburgh Postnatal Depression Scale (EPDS): translation and validation study of the Iranian version. BMC Psychiatry.2007;7:11	Data could not be extracted (Sensitivity and specificity could not be extracted)

Morales CF, Campillo GG. Adjustment of the IDARE anxiety instrument in pregnant women. Revista Mexicana de Psicologia. 1990;7:75-80	Not in English
Murray L, Carothers AD. The validation of the Edinburgh Post-natal Depression Scale on a community sample. British Journal of Psychiatry. 1990a;157:288-290	Data could not be extracted
Navarro P, Ascaso C, Garcia-Esteve L, Aguado J, Torres A, Martin-Santos R. Postnatal psychiatric morbidity: a validation study of the GHQ-12 and the EPDS as screening tools. General Hospital Psychiatry. 2007;29: 1-7	Data could not be extracted (Data for 'Postnatal psychiatric morbidity'- does not diaggregate data by depression, anxiety or other disroders)
Petersen, J. J., et al. (2009). "A survey on worries of pregnant women--testing the German version of the Cambridge worry scale." BMC public health 9: 490.	Abstract
Pollock JI., Manaseki-Holland S, Patel V. Detection of depression in women of child-bearing age in non-western cultures: A comparison of the Edinburgh Postnatal Depression Scale and the Self-Reporting Questionnaire-20 in Mongolia. Journal of Affective Disorders. 2006;92:267-271.	Not a perinatal population (women of child-bearing age)
Posner NA, Unterman RR, Williams, KN, Williams GH. Screening for postpartum depression: An antepartum questionnaire. Journal of Reproductive Medicine for the Obstetrician and Gynecologist. 1997; 42:207-215	No relevant outcomes
Righetti-Veltema M, Conne-Perreard E, Bousquet A, Manzano Construction and multicentric validation of an antepartum screening questionnaire for postpartum depression." La Psychiatrie de l'Enfant. 2006;49: 513-541	Not in English
Rochat TJ, Tomlinson M, Newell ML, Stein A. Detection of antenatal depression in rural hiv-affected populations with short and ultrashort versions of the edinburgh postnatal depression scale (epds). Archives of Women's Mental Health.	Population not relevant (HIV population)
Rowel D, Jayawardena P, Fernando N. Validation of the Sinhala translation of Edinburgh Postnatal Depression Scale. The Ceylon medical journal. 2008:53;10-13	Data could not be extracted
Sagrestano, L.M., Rodriguez, A.C., Carroll, D., Bieniarz, A., Greenberg, A., Castro, L., Nuwayhid, B., 2002. A comparison of standardized measures of psychosocial variables with single-item screening measures used in an urban obstetric clinic. J. Obstet. Gynecol. Neonatal Nurs. 31, 147-155.	No relevant outcomes
Stewart RC, Umar E, Tomenson B, Creed F. Validation of screening tools for antenatal depression in Malawi-A comparison of the Edinburgh Postnatal Depression Scale and Self Reporting Questionnaire. Journal of Affective Disorders. 2013:150;1041-1047	Data could not be extracted
Swallow BL, Lindow SW, Masson EA, Hay DM. The use of the General Health Questionnaire (GHQ-28) to estimate prevalence of psychiatric disorder in early pregnancy. Psychology, Health and Medicine. 2003; 8:213-217.	Over 12 items
Vega-Dienstmaier JM, Mazzotti SG, Campos S. Validation of a Spanish version of the Edinburgh Postnatal Depression Scale. Actas Esp Psiquiatr. 2002;30: 106-111	Not in English

Venkatesh KK, Zlotnick C, Triche EW, Ware C, Phipps MG. Accuracy of brief screening tools for identifying postpatrum depression among adolescent mothers. Pediatrics.2014;133:e45-53	Adolescent population not appropriate
Vivilaki VG, Dafermos V, Kogevinas M, Bitsios P, Lionis C. The Edinburgh Postnatal Depression Scale: translation and validation for a Greek sample. BMC public health. 2009; 9:329.	Abstract
Wallis AB, Fernandez R, Oprescu F, Chereches R, Zlati A, Dungy CI. Validation of a Romanian scale to detect antenatal depression." Central European Journal of Medicine. 2012;7:216-223.	No gold standard
Wa YI. Martin CR. Psychometric properties of the 12-item General Health Questionnaire (GHQ-12) in Chinese women during pregnancy and in the postnatal period. Psychology, Health and Medicine. 2006; 11: 60-69.	No gold standard
Webster, J. A simplified predictive index for the detection of women at risk for postnatal depression. Birth. 2003; 30: 101-108.	No gold standard
Weobong B, Akpalu B, Doku V, Owusu-Agyei S, Hurt L, Kirkwood B, et al. The comparative validity of screening scales for postnatal common mental disorder in Kintamp, Ghana. Journal of Affective Disorders. 2009;113:109–117.	No gold standard
Zelkowitz P, Milet TH. Screening for post-partum depression in a community sample. Canadian Journal of Psychiatry. 1995:40;80-86	Data could not be extracted
Zubaran C, Foresti K, Schumacher MV, Amoretti AL, Muller LC, Thorell MR. Validation of a screening instrument for postpartum depression in Southern Brazil. Journal of Psychosomatic Obstetrics and Gynecology. 2009; 30: 244-254.	Over 12 items

1.3 EXPERIENCE OF CARE – INCLUDED STUDIES

1.3.1 ANTONYSAMY2009

Study ID	ANTONYSAMY2009
Bibliographic reference	Antonysamy A, Wieck A, Wittkowski A. Service satisfaction on discharge from a psychiatric mother and baby unit: a representative patient survey. Archives of Women's Mental Health. 2009;12: 359-362.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** 39% schizophrenia or schizo-affective disorder; 18% bipolar disorder; 25% depresssion with or without psychotic symptoms; 4% OCD; 4% personality disorder; 12% other diagnoses (ICD-10) **N:** 57 **Mean maternal age (years):** 46% 26-35 (25% younger; 30% older) **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** 65 **Method of delivery:** Not reported
Treatment details	Mother and Baby Unit at Wythenshawe Hospital in Manchester, England. This is a specialised inpatient unit that admits women with moderate to severe mental illness within one year of childbirth from Greater Manchester and neighbouring districts
Focus of study	Experience of inpatient unit
Study design	Mixed method (Qualitative)
Notes	None

1.3.2 AYERS2006

Study ID	AYERS2006
Bibliographic reference	Ayers S, Eagle A, Waring H. The effects of childbirth-related post-traumatic stress disorder on women and their relationships: a qualitative study. Psychology, Health and Medicine. 2006;11:389-398.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** PTSD (PTSD Diagnostic Scale) **N:** 6 **Mean maternal age (years):** Not reported (range: 22-37) **Mean age of child:** 7.1 years (retrospective experience of birth) **Primiparous (%):** 67 **Ethnicity (% white):** Not reported **Method of delivery:** 50% vaginal; 50% emergency caesarean
Treatment details	N/A
Focus of study	Factors that diminish EoC
Study design	Qualitative

Notes	None

1.3.3 BOATH2004

Study ID	BOATH2004
Bibliographic reference	Boath E, Bradley E, Henshaw C. Women's views of antidepressants in the treatment of postnatal depression. Journal of Psychosomatic Obstetrics and Gynecology. 2004;25:221-233.
Methods	**Data collection method:** Questionnaire (open-ended) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** Depression (EPDS>12 & Research Diagnostic Criteria [following Standardised Psychiatric Interview]) **N:** 35 **Mean maternal age (years):** 27.3 **Mean age of child:** 22.9 weeks **Primiparous (%):** 43 **Ethnicity (% white):** 100 **Method of delivery:** 89% vaginal; 11% caesarean
Treatment details	14% SSRIs; 71% TCAs
Focus of study	Experience of antidepressants
Study design	Qualitative
Notes	None

1.3.4 BREUSTEDT2013

Study ID	BREUSTEDT2013
Bibliographic reference	Breustedt S, Puckering C. A qualitative evaluation of women's experiences of the mellow bumps antenatal intervention. British Journal of Midwifery. 2013;21:187-194.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 4 **Mean maternal age (years):** 27.75 **Mean age of child:** 8.2 months **Primiparous (%):** 75 **Ethnicity (% white):** 75 **Method of delivery:** Not reported
Treatment details	Mellow Bumps antenatal intervention for pregnant women with psychosocial risk factors
Focus of study	Factors that improve EoC
Study design	Qualitative
Notes	None

1.3.5 CHEWGRAHAM2009

Study ID	CHEWGRAHAM2009
Bibliographic reference	Chew-Graham CA, Sharp D, Chamberlain E, Folkes L, Turner KM. Disclosure of symptoms of postnatal depression, the perspectives of health professionals and women: a qualitative study. BMC Family Practice. 2009;10:7.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Depression (EPDS>11 & CIS-R) **N:** 28 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	Antidepressants compared with listening visits (RESPOND trial)
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.6 COOKE2012

Study ID	COOKE2012
Bibliographic reference	Cooke S, Smith I, Turl E, Arnold E, Msetfi RM. Parent perspectives of clinical psychology access when experiencing distress. Community Practitioner. 2012;85:34-37.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** All participants self-identified as having experienced emotional distress within their baby's first year (and within the last 2 years) **N:** 7 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported (<1 year [includes retrospective experiences]) **Primiparous (%):** 71 **Ethnicity (% white):** 57 **Method of delivery:** Not reported
Treatment details	14% had accessed clinical psychology; 14% had accessed mental health crisis team; 86% had accessed local authority outreach; 29% had accessed primary care services (NB: a minority of participants had accessed multiple services)
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.7 DEJONGE2001

Study ID	DEJONGE2001
Bibliographic reference	de Jonge A. Support for teenage mothers: a qualitative study into the views of women about the support they received as teenage mothers. Journal of Advanced Nursing. 2001;36:49-57.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 33% depression; 8% drinking problem **N:** 12 **Mean maternal age (years):** Not reported (range: 19-40, median: 26. Age when first child born: range: 16-19, median: 17) **Mean age of child:** Not reported **Primiparous (%):** 55 **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.8 EDGE2005/2007/2008

Study ID	EDGE2005/2007/2008
Bibliographic reference	Edge D, Rogers A. Dealing with it: Black Caribbean women's response to adversity and psychological distress associated with pregnancy, childbirth, and early motherhood. Social Science and Medicine. 2005;61:15-25. Edge D. Perinatal depression and Black Caribbean women: lessons for primary care. Primary Health Care. 2007;17:32-35. Edge D. 'We don't see Black women here': an exploration of the absence of Black Caribbean women from clinical and epidemiological data on perinatal depression in the UK. Midwifery. 2008;24:379-389.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 17% antenatal depression (antenatal EPDS mean: 17.5); 25% postnatal depression (postnatal EPDS mean: 18.3); 17% depressed during and after pregnancy (antenatal and postnatal EPDS mean: 21.5 & 19.5; 42% Never depressed **N:** 12 **Mean maternal age (years):** 31.8 **Mean age of child:** Not reported (range: 0.5-1 year) **Primiparous (%):** Not reported **Ethnicity (% white):** 0 **Method of delivery:** Not reported

Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.9 EDGE2011

Study ID	EDGE2011
Bibliographic reference	Edge D. 'It's leaflet, leaflet, leaflet then, "see you later"': black Caribbean women's perceptions of perinatal mental health care. British Journal of General Practice. 2011;61:256-262.
Methods	**Data collection method:** Focus group **Setting:** Multiple (Home, Community settings) **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 42 **Mean maternal age (years):** Not reported (range: 18-43) **Mean age of child:** Not reported (majority <2 years) **Primiparous (%):** Not reported **Ethnicity (% white):** 0 **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.10 EDWARDS2005

Study ID	EDWARDS2005
Bibliographic reference	Edwards E, Timmons S. A qualitative study of stigma among women suffering postnatal illness. Journal of Mental Health. 2005;14:471–481.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 50% postpartum psychosis; 33% severe depression; 17% depressive psychosis (diagnosed by consultant psychiatrist) **N:** 6 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	Mother and baby unit, an inpatient service which forms part of the Motherhood and Mental Health Service in a UK National Health Service (NHS) hospital
Focus of study	Barriers to access

Study design	Qualitative
Notes	None

1.3.11 HALL2006

Study ID	HALL2006
Bibliographic reference	Hall P. Mothers' experiences of postnatal depression: an interpretative phenomenological analysis. Community Practitioner. 2006;79:256-260.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Child and family centre, GP clinic, or home **Country:** UK
Participants	**Axis I/II disorders:** PND (EPDS>12 on two consecutive occasions) **N:** 10 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** 50 **Ethnicity (% white):** 90 **Method of delivery:** Not reported
Treatment details	Not reported
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.12 HANLEY2006

Study ID	HANLEY2006
Bibliographic reference	Hanley J, Long B. A study of Welsh mothers' experiences of postnatal depression. Midwifery. 2006;22:147-157.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Depression (EPDS=>12 & clinical diagnosis) **N:** 10 **Mean maternal age (years):** Not reported (range: 17-33) **Mean age of child:** Not reported **Primiparous (%):** 40 **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Factors that improve EoC
Study design	Qualitative
Notes	None

1.3.13 HERON2012

Study ID	HERON2012
Bibliographic reference	Heron J, Gilbert N, Dolman C, Shah S, Beare I, Dearden S, et al. Information and support needs during recovery from postpartum psychosis. Archives of Women's Mental Health. 2012;15:155-165.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** Postpartum Psychosis (PP) **N:** 5 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported (5-20 years since episode [retrospective experience]) **Primiparous (%):** Not reported **Ethnicity (% white):** 100 **Method of delivery:** Not reported
Treatment details	20% Mother and baby unit; 40% General psychiatric unit without baby; 20% Private hospital without baby; 20% General psychiatric unit briefly and intensive home treatment
Focus of study	Experience of inpatient unit
Study design	Qualitative
Notes	None

1.3.14 HUNT2009

Study ID	HUNT2009
Bibliographic reference	Hunt K, France E, Ziebland S, Field K, Wyke S. 'My brain couldn't move from planning a birth to planning a funeral': a qualitative study of parents' experiences of decisions after ending a pregnancy for fetal abnormality. International Journal of Nursing Studies. 2009;46:1111-1121.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 42 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** 88% non-surgical termination; 12% surgical termination
Treatment details	Termination following diagnosis of fetal abnormality. As the majority of fetal abnormalities had been detected or confirmed well into the second trimester of pregnancy, most pregnancies had ended with an induced labour
Focus of study	Experience of termination of pregnancy following diagnosis of fetal abnormality
Study design	Qualitative

Notes	None

1.3.15 MAPP2005A/2005B

Study ID	MAPP2005A/2005B
Bibliographic reference	Mapp T, Hudson K. Feelings and fears during obstetric emergencies, part1. British Journal of Midwifery. 2005a;13:30–35. Mapp T. Feelings and fears post obstetric emergencies, part2. British Journal of Midwifery. 2005b;13:36–40.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home or hospital **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 10 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported (<3 years since obstetric emergency) **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	All of the participants had experienced an obstetric emergency within the last three years: 10% experienced an eclamptic fit; 50% experienced placental abruptions; 70% experienced major postpartum haemorrhage and for 20% this resulted on hysterectomy
Focus of study	Experience of obstetric emergency
Study design	Qualitative
Notes	None

1.3.16 MCCREIGHT2008

Study ID	MCCREIGHT2008
Bibliographic reference	McCreight BS. Perinatal loss: a qualitative study in Northern Ireland. Omega. 2008;57:1-19.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 23 **Mean maternal age (years):** Not reported (range: 19-60 [retrospective experiences]) **Mean age of child:** Not reported (time since pregnancy loss: 0.2-34 years [78% had experienced pregnancy loss = <3 years previously]) **Primiparous (%):** 9% had no living children **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	All participants had experienced pregnancy loss: 35% had experienced

	stillbirth; 35% had experienced both stillbirth and miscarriage; 26% had experienced miscarriage; 4% had experienced twin stillbirths
Focus of study	Experience of pregnancy loss due to stillbirth or miscarriage
Study design	Qualitative
Notes	None

1.3.17 MCGRATH2013

Study ID	MCGRATH2013
Bibliographic reference	McGrath L, Peters S, Wieck A, Wittkowski A. The process of recovery in women who experienced psychosis following childbirth. BMC Psychiatry. 2013;13:341.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** 92% postpartum psychosis; 8% depression with psychotic features (self-report and where possible verification with medical records) **N:** 12 **Mean maternal age (years):** 35.6 **Mean age of child:** 5.5 years (retrospective experiences of psychosis following childbirth) **Primiparous (%):** Not reported **Ethnicity (% white):** 100 **Method of delivery:** Not reported
Treatment details	33% general psychiatric ward; 17% initially admitted to general psychiatric ward and then transferred to mother and baby unit; 17% remained on maternity ward; 8% received care at home
Focus of study	Factors that diminish EoC
Study design	Qualitative
Notes	None

1.3.18 NICHOLLS2007

Study ID	NICHOLLS2007
Bibliographic reference	Nicholls K, Ayers S. Childbirth-related post-traumatic stress disorder in couples: a qualitative study. British Journal of Health Psychology. 2007;12:491–509.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 83% PTSD (PTSD Diagnostic Scale [PDS]) **N:** 6 **Mean maternal age (years):** Not reported (not possible to extract disaggregated woman data from couple data) **Mean age of child:** Not reported (range: 0.75-10 years [retrospective

	experience of traumatic birth]) **Primiparous (%):** 83 **Ethnicity (% white):** 100 **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Factors that diminish EoC
Study design	Qualitative
Notes	None

1.3.19 PARVIN2004

Study ID	PARVIN2004
Bibliographic reference	Parvin A, Jones CE, Hull SA. Experiences and understandings of social and emotional distress in the postnatal period among Bangladeshi women living in Tower Hamlets. Family Practice. 2004;21:254-260.
Methods	**Data collection method:** Focus group **Setting:** Community setting **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 25 **Mean maternal age (years):** 34.3 **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** 0 **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.20 PATEL2013

Study ID	PATEL2013
Bibliographic reference	Patel S, Wittkowski A, Fox JR, Wieck A. An exploration of illness beliefs in mothers with postnatal depression. Midwifery. 2013;29:682-689.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** Depression (EPDS 12-23; mean: 15) **N:** 11 **Mean maternal age (years):** 29.4 **Mean age of child:** 8.9 months **Primiparous (%):** 45 **Ethnicity (% white):** 100 **Method of delivery:** 45% natural; 18% forceps; 36% C-section
Treatment details	36% antidepressants and CBT; 18% antidepressants and CBT (inpatient

	treatment); 9% antidepressants (inpatient); 9% CBT; 9% antidepressants, counselling, group-based CBT; 9% antidepressants, counselling, group support; 9% Group and specialist mental health support
Focus of study	Experience of antidepressants
Study design	Qualitative
Notes	None

1.3.21 RAYMOND2009

Study ID	RAYMOND2009
Bibliographic reference	Raymond JE. 'Creating a safety net': women's experiences of antenatal depression and their identification of helpful community support and services during pregnancy. Midwifery. 2009;25:39-49.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Multiple (Home, Community settings) **Country:** UK
Participants	**Axis I/II disorders:** Antenatal depression **N:** 9 **Mean maternal age (years):** 29.1 **Mean age of child:** Not reported (inclusion criteria 6 weeks-1 year) **Primiparous (%):** 56 **Ethnicity (% white):** 67 **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Modifications that improve EoC
Study design	Qualitative
Notes	None

1.3.22 ROBERTSON2003

Study ID	ROBERTSON2003
Bibliographic reference	Robertson E, Lyons A. Living with puerperal psychosis: a qualitative analysis. Psychology and Psychotherapy. 2003;76:411–431.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Postpartum psychosis (DSM-IV) **N:** 10 **Mean maternal age (years):** 34 **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Factors that diminish EoC

Study design	Qualitative
Notes	None

1.3.23 RYNINKS2014

Study ID	RYNINKS2014
Bibliographic reference	Ryninks K, Roberts-Collins C, McKenzie-McHarg K, Horsch A. Mothers' experience of their contact with their stillborn infant: an interpretative phenomenological analysis. BMC Pregnancy and Childbirth. 2014;14:203.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 21 **Mean maternal age (years):** 34.4 **Mean age of child:** 3 months post-stillbirth (+/- 1 week) **Primiparous (%):** Not reported **Ethnicity (% white):** 95 **Method of delivery:** Not reported
Treatment details	All women had experienced a stillbirth (occurring on average at 35 weeks gestational age) and all women had seen their stillborn baby and 91% had held their baby
Focus of study	Experience of stillbirth
Study design	Qualitative
Notes	None

1.3.24 SHAKESPEARE2003

Study ID	SHAKESPEARE2003
Bibliographic reference	Shakespeare J, Blake F, Garcia J. A qualitative study of the acceptability of routine screening of postnatal women using the Edinburgh Postnatal Depression Scale. British Journal of General Practice. 2003;53:614-619.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 20.5% PND (EPDS=>13) at 8 weeks; 10% PND (EPDS=>13) at 8 months; 33% PND (using listening visits as proxy) **N:** 39 **Mean maternal age (years):** 34 **Mean age of child:** 15 months **Primiparous (%):** 33 **Ethnicity (% white):** 95 **Method of delivery:** 69% normal; 5% ventouse; 26% caesarean
Treatment details	Routine screening with EPDS
Focus of study	Experience of routine screening with EPDS

Study design	Qualitative
Notes	None

1.3.25 SHAKESPEARE2006

Study ID	SHAKESPEARE2006
Bibliographic reference	Shakespeare J, Blake F, Garcia J. How do women with postnatal depression experience listening visits in primary care? a qualitative interview study. Journal of Reproductive and Infant Psychology. 2006;24:149-162.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 62.5% PND (EPDS=>13 at 8 weeks or 8 months or both); 75% PND (self-report) **N:** 16 **Mean maternal age (years):** 32 **Mean age of child:** 15 months **Primiparous (%):** 37.5 **Ethnicity (% white):** 100 **Method of delivery:** 75% normal; 6% ventouse; 19% caesarean
Treatment details	100% Listening visits; 37.5% had also had antidepressants prescribed
Focus of study	Experience of listening visits
Study design	Qualitative
Notes	None

1.3.26 SIMMONS2006

Study ID	SIMMONS2006
Bibliographic reference	Simmons RK, Singh G, Maconochie N, Doyle P, Green J. Experience of miscarriage in the UK: qualitative findings from the National Women's Health Study. Social Science and Medicine.2006;63:1934-1946.
Methods	**Data collection method:** Questionnaire (open-ended) **Setting:** Postal questionnaire **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 280 **Mean maternal age (years):** 31 **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Experience of post-miscarriage information and support
Study design	Qualitative
Notes	None

1.3.27 SLADE2010

Study ID	SLADE2010
Bibliographic reference	Slade P, Morrell CJ, Rigby A, Ricci K, Spittlehouse J, Brugha TS. Postnatal women's experiences of management of depressive symptoms: a qualitative study. British Journal of General Practice. 2010;60:e440-e448.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** PND (EPDS=>18) **N:** 30 **Mean maternal age (years):** Not reported (25% 18-25; 54% 26-35; 21% 36-45) **Mean age of child:** 6 months **Primiparous (%):** 70 **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	60% antidepressants; 27% anidepressants and psychological intervention (13.3% antidepressants & person-centred approach [PCA]; 13.3% antidepressants & cognitive-behavioural approach [CBA]); 7% psychological intervention only (3.3% PCA; 3.3% CBA)
Focus of study	Factors that improve EoC
Study design	Qualitative
Notes	None

1.3.28 SMITH2007

Study ID	SMITH2007
Bibliographic reference	Smith L, Gibb S. Postnatal support for drug users: evaluation of a specialist health visiting service. Community Practitioner. 2007;80:24-29.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** All participants were being treated for substance misuse **N:** 9 **Mean maternal age (years):** Not reported (range: 19-30) **Mean age of child:** Not reported (range: 2-8 weeks) **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	All participants were following a methadone programme
Focus of study	Experience of a specialist health visiting service
Study design	Qualitative
Notes	None

1.3.29 SNOWDON2012

Study ID	SNOWDON2012
Bibliographic reference	Snowdon C, Elbourne D, Forsey M, Alfirevic Z. Information-hungry and disempowered: a qualitative study of women and their partners' experiences of severe postpartum haemorrhage. Midwifery. 2012;28:791–799.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 9 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** 33 **Ethnicity (% white):** Not reported **Method of delivery:** 22% planned C-section and 78% emergency C-section
Treatment details	N/A
Focus of study	Experience of traumatic birth
Study design	Qualitative
Notes	None

1.3.30 STANLEY2006

Study ID	STANLEY2006
Bibliographic reference	Stanley N, Borthwick R, Macleod A. Antenatal depression: mothers' awareness and professional responses. Primary Health Care Research and Development. 2006;7:257-268.
Methods	**Data collection method:** Focus group **Setting:** Community setting **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 28 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported (inclusion criteria <2 years) **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.31 STAPLETON2008

Study ID	STAPLETON2008
Bibliographic reference	Stapleton H, Fielder A, Kirkham M. Breast or bottle? eating disordered

	childbearing women and infant-feeding decisions. Maternal and Child Nutrition. 2008;4:106-120.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Eating disorder (self-report) **N:** 16 **Mean maternal age (years):** Not reported (range: 23-44) **Mean age of child:** Not reported (inclusion criteria <2 years) **Primiparous (%):** Not reported **Ethnicity (% white):** 100 **Method of delivery:** Not reported
Treatment details	94% medical treatment including psychotherapy and prescribed medication
Focus of study	Factors that diminish EoC
Study design	Qualitative
Notes	None

1.3.32 TEMPLETON2003

Study ID	TEMPLETON2003
Bibliographic reference	Templeton L, Velleman R, Persaud A, Milner P. The experiences of postnatal depression in women from black and minority ethnic communities in Wiltshire, UK. Ethnicity and Health. 2003;8:207-221.
Methods	**Data collection method:** Focus group and interview **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** Interview sample (N=6): PND (EPDS=>10) **N:** 20 **Mean maternal age (years):** Not reported **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** 0 **Method of delivery:** Not reported
Treatment details	N/A
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.33 THOMSON2008

Study ID	THOMSON2008
Bibliographic reference	Thomson G, Downe S. Widening the trauma discourse: the link between childbirth and experiences of abuse. Journal of Psychosomatic Obstetrics and Gynecology. 2008;29:268-273.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported

	Country: UK
Participants	**Axis I/II disorders:** Not reported **N:** 14 **Mean maternal age (years):** Not reported (range: 27-40) **Mean age of child:** Not reported (range: 1.3-19 years [retrospective experience of birth]) **Primiparous (%):** 93 **Ethnicity (% white):** 93 **Method of delivery:** 71% forceps or caesarean; 29% uncomplicated vaginal deliveries
Treatment details	After birth services
Focus of study	Experience of traumatic birth
Study design	Qualitative
Notes	None

1.3.34 THOMSON2013

Study ID	THOMSON2013
Bibliographic reference	Thomson G, Downe S. A hero's tale of childbirth. Midwifery. 2013;29:765-771.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 12 **Mean maternal age (years):** Not reported (range: 27-40) **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** 92 **Method of delivery:** 83% forceps or caesarean; 17% uncomplicated vaginal deliveries
Treatment details	After birth services
Focus of study	Experience of traumatic birth
Study design	Qualitative
Notes	None

1.3.35 THURTLE2003

Study ID	THURTLE2003
Bibliographic reference	Thurtle V. First time mothers' perceptions of motherhood and PND. Community Practitioner. 2003;76:261-265.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** 7% of sample scored >12 on EPDS; 36% felt they were (or had been) depressed **N:** 14

	Mean maternal age (years): Not reported (range: 17-38; 'majority in their 30s') **Mean age of child:** Not reported **Primiparous (%):** 100 **Ethnicity (% white):** Not reported **Method of delivery:** 43% normal delivery; 29% caesarean; 14% ventouse; 14% forceps
Treatment details	Not reported
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.3.36 TSARTSARA2002

Study ID	TSARTSARA2002
Bibliographic reference	Tsartsara E, Johnson MP Women's experience of care at a specialised miscarriage unit: an interpretive phenomenological study. Clinical Effectiveness in Nursing. 2002;6:55–65.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** Not reported **N:** 6 **Mean maternal age (years):** 34.9 **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** Not reported **Method of delivery:** Not reported
Treatment details	Early Pregnancy Assessment Unit (EPAU; specialised miscarriage unit)
Focus of study	Experience of post-miscarriage information and support
Study design	Qualitative
Notes	None

1.3.37 TURNER2008

Study ID	TURNER2008
Bibliographic reference	Turner KM, Sharp D, Folkes L, Chew-Graham C. Women's views and experiences of antidepressants as a treatment for postnatal depression: a qualitative study. Family Practice. 2008;25:450-455.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** PND (EPDS>12 & Clinical Interview Schedule [Revised]) **N:** 27 **Mean maternal age (years):** Not reported (range: 19-45) **Mean age of child:** Not reported ('just over 1 year')

	Primiparous (%): Not reported **Ethnicity (% white):** 78 **Method of delivery:** Not reported
Treatment details	11% antidepressants; 33% counselling; 48% counselling and antidepressants; 7% neither antidepressants nor counselling
Focus of study	Experience of antidepressants
Study design	Qualitative
Notes	None

1.3.38 TURNER2010

Study ID	TURNER2010
Bibliographic reference	Turner KM, Chew-Graham C, Folkes L, Sharp D. Women's experiences of health visitor delivered listening visits as a treatment for postnatal depression: a qualitative study. Patient Education and Counseling. 2010;78:234-239.
Methods	**Data collection method:** Interview (face-to-face) **Setting:** Home **Country:** UK
Participants	**Axis I/II disorders:** PND (EPDS>12 & Clinical Interview Schedule [Revised]). EPDS at baseline 14-26 (mean: 17.6) **N:** 22 **Mean maternal age (years):** Not reported (range: 19-45) **Mean age of child:** Not reported **Primiparous (%):** Not reported **Ethnicity (% white):** 73 **Method of delivery:** Not reported
Treatment details	Listening visits (up to 8 sessions)
Focus of study	Experience of listening visits
Study design	Qualitative
Notes	None

1.3.39 WITTKOWSKI2011

Study ID	WITTKOWSKI2011
Bibliographic reference	Wittkowski A, Zumla A, Glendenning S, Fox JRE. The experience of postnatal depression in South Asian mothers living in Great Britain: a qualitative study. Journal of Reproductive and Infant Psychology. 2011;29:480-492.
Methods	**Data collection method:** Interview (format not reported) **Setting:** Not reported **Country:** UK
Participants	**Axis I/II disorders:** PND (EPDS>12).EPDS range 17-23 (mean: 19.6) **N:** 10 **Mean maternal age (years):** Not reported **Mean age of child:** 2.2 months **Primiparous (%):** Not reported **Ethnicity (% white):** 0

	Method of delivery: Not reported
Treatment details	Not reported
Focus of study	Barriers to access
Study design	Qualitative
Notes	None

1.4 EXPERIENCE OF CARE – EXCLUDED STUDIES

Study	Reason for exclusion
Abboud L, Liamputtong P. When pregnancy fails: coping strategies, support networks and experiences with health care of ethnic women and their partners. Journal of Reproductive and Infant Psychology. 2005;23:3-18.	Non-UK study
Ackerson BJ Coping with the dual demands of severe mental illness and parenting: the parents' perspective. Family and Society. 2003;84:109–118.	Non-UK study
Ahmed A, Stewart DE, Teng L, Wahoush O, Gagnon AJ. Experiences of immigrant new mothers with symptoms of depression. Archives of Women's Mental Health. 2008;11:295-303.	Non-UK study
Anderson CM, Robins CS, Greeno CG, Cahalane H, Copeland VC, Andrews RM. Why lower income mothers do not engage with the formal mental health care system: perceived barriers to care. Qualitative Health Research. 2006;16:926-943.	Non-UK study
Anderson LN. Functions of support group communication for women with postpartum depression: how support groups silence and encourage voices of motherhood. Journal of Community Psychology. 2013;41:709-724.	Non-UK study
Ayers S. Thoughts and emotions during traumatic birth: a qualitative study. Birth. 2007: 34, 253-263.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Balaam M-C, Akerjordet K, Lyberg A, Kaiser B, Schoening E, Fredriksen AM, et al. A qualitative review of migrant women's perceptions of their needs and experiences related to pregnancy and childbirth. Journal of Advanced Nursing. 2013;69:1919-1930.	Systematic review with no new useable data
Barlow JH, Hainsworth JM, Thornton S. An exploratory, descriptive study of women's experiences of hospital admission during pre-term labor. Acta Obstetricia et Gynecologica Scandinavica. 2007;86:429-434.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Barrell M. Adolescent motherhood in an inner city area in the UK: experiences and needs of a group of adolescent mothers. The Practising Midwife. 2003;6:21-24.	Not mental health-focused
Battle CL, Salisbury AL, Schofield CA, Ortiz-Hernandez S. Perinatal antidepressant use: understanding women's preferences and concerns. Journal of Psychiatric Practice. 2013;19:443-453.	Non-UK study
Baum N, Weidberg Z, Osher Y, Kohelet D. No longer pregnant, not yet a mother: giving birth prematurely to a very-low-birth-weight baby. Qualitative Health Research. 2012;22:595-606.	Non-UK study
Beck CT. Postpartum depression: a metasynthesis. Qualitative Health Research. 2002;12:453-472.	Systematic review with no new useable data
Beck CT. Post-traumatic stress disorder due to childbirth: the aftermath. Nursing Research. 2004a;53:216-224.	Non-UK study
Beck CT. Birth trauma: in the eye of the beholder. Nursing Research. 2004b;53:28-35.	Non-UK study
Beck CT. Benefits of participating in internet interviews: women helping women. Qualitative Health Research. 2005;15:411-422.	Non-UK study
Beck CT. The anniversary of birth trauma: failure to rescue. Nursing Research. 2006a;55:381-390.	Non-UK study

Beck CT. Pentadic cartography: mapping birth trauma narratives. Qualitative Health Research. 2006b;16:453-466.	Non-UK study
Beck CT, Watson S. Impact of birth trauma on breast-feeding: a tale of two pathways. Nursing Research. 2008;57:228-236.	Non-UK study
Bennett IM, Palmer S, Marcus S, Nicholson JM, Hantsoo L, Bellamy S, et al. "One end has nothing to do with the other:" patient attitudes regarding help seeking intention for depression in gynecologic and obstetric settings. Archives of Women's Mental Health. 2009;12:301-308.	Non-UK study
Bilszta J, Ericksen J, Buist A, Milgrom J. Women's experience of postnatal depression – beliefs and attitudes as barriers to care. Australian Journal of Advanced Nursing. 2010;27:44-54.	Non-UK study
Blanchard A, Hodgson J, Gunn W, Jesse E, White M. Understanding social support and the couple's relationship among women with depressive symptoms in pregnancy. Issues in Mental Health Nursing. 2009;30:764-776.	Non-UK study
Brealey SD, Hewitt C, Green JM, Morrell J, Gilbody S. Screening for postnatal depression – is it acceptable to women and healthcare professionals? A systematic review and meta-synthesis. Journal of Reproductive and Infant Psychology. 2010;28:328-344.	Systematic review with no new useable data
Briscoe L, Lavender T. Exploring maternity care for asylum seekers and refugees. British Journal of Midwifery. 2009;17:17–23.	Not mental health-focused
Bullock LF, Browning C, Geden E. Telephone social support for low-income pregnant women. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2002;31:658-664.	Non-UK study
Buultjens M, Robinson P, Liamputtong P. A holistic programme for mothers with postnatal depression: pilot study. Journal of Advanced Nursing. 2008;63:181-188.	Non-UK study
Byatt N, Biebel K, Friedman L, Debordes-Jackson G, Ziedonis D. Women's perspectives on postpartum depression screening in pediatric settings: a preliminary study. Archives of Women's Mental Health. 2013a;16:429-432.	Non-UK study
Byatt N, Biebel K, Friedman L, Debordes-Jackson G, Ziedonis D. Patient's views on depression care in obstetric settings: how do they compare to the views of perinatal health care professionals? General Hospital Psychiatry. 2013b;35:598-604.	Non-UK study
Caelli K, Downie J, Letendre A. Parents' experiences of midwife-managed care following the loss of a baby in a previous pregnancy. Journal of Advanced Nursing. 2002;39:127-136.	Non-UK study
Chernomas WM, Clarke DE, Chisholm FA. Perspectives of women living with schizophrenia. Psychiatric Services. 2000;51:1517–1521.	Non-UK study
Clemmens DA. Adolescent mothers' depression after the birth of their babies: weathering the storm. Adolescence. 2002;37:551-565.	Non-UK study
Corbet-Owen C, Kruger LM. The health system and emotional care: validating the many meanings of spontaneous pregnancy loss. Families, Systems and Health. 2001;19:411-427.	Non-UK study
Côte-Arsenault D, Marshall R. One foot in – one foot out: weathering the storm of pregnancy after perinatal loss. Research in Nursing and Health. 2000;23:473-485.	Non-UK study
Côté-Arsenault D, Bidlack D, Humm A. Women's emotions and concerns during pregnancy following perinatal loss. The American Journal of Maternal Child Nursing. 2001;26:128-134.	Non-UK study
Côté-Arsenault D, Freije MM. Support groups helping women through	Non-UK study

pregnancies after loss. Western Journal of Nursing Research. 2004;26:650-670.	
Davies B, Allen D. Integrating 'mental illness' and 'motherhood': the positive use of surveillance by health professionals. A qualitative study. International Journal of Nursing Studies. 2007;44:365–376.	Experience of care greater than one year into the postnatal period
Dennis CL, Chung-Lee L. Postpartum depression help-seeking barriers and maternal treatment preferences: a qualitative systematic review. Birth. 2006;33:323-331.	Systematic review with no new useable data
Dennis TR, Moloney MF. Surviving postpartum depression and choosing to be a mother. Southern Online Journal of Nursing Research. 2009;9:Article 6.	Non-UK study
Dennis C-L. Postpartum depression peer support: maternal perceptions from a randomized controlled trial. International Journal of Nursing Studies. 2010;47:560-568.	Non-UK study
Diaz-Caneja A, Johnson S. The views and experiences of severely mentally ill mothers—a qualitative study. Social Psychiatry and Psychiatric Epidemiology. 2004;39:472–482.	Experience of care greater than one year into the postnatal period
Dolman C, Jones I, Howard LM. Pre-conception to parenting: a systematic review and meta-synthesis of the qualitative literature on motherhood for women with severe mental illness. Archives of Women's Mental Health. 2013;16:173-196.	Systematic review with no new useable data
Edge D, MacKian SC. Ethnicity and mental health encounters in primary care: help-seeking and help-giving for perinatal depression among Black Caribbean women in the UK. Ethnicity and Health. 2010;15:93-111.	Same sample as EDGE2005/2007/2008 and no new data to extract
Elmir R, Schmied V, Wilkes L, Jackson D. Women's perceptions and experiences of a traumatic birth: a meta-ethnography. Journal of Advanced Nursing. 2010;66:2142-2153.	Systematic review with no new useable data
Eriksson BS, Pehrsson G. Emotional reactions of parents after the birth of an infant with extremely low birth weight. Journal of Child Health Care. 2005;9:122-136.	Non-UK study
Erlandsson K, Lindgren H, Malm MC, Davidsson-Bremborg A, Rådestad I. Mothers' experiences of the time after the diagnosis of an intrauterine death until the induction of the delivery: a qualitative Internet-based study. Journal of Obstetrics and Gynaecology Research. 2011;37:1677-1684.	Internet-based survey (unclear if relevant to UK)
Feinberg E, Smith MV, Naik R. Ethnically diverse mothers' views on the acceptability of screening for maternal depressive symptoms during pediatric well-child visits. Journal of Health Care for the Poor and Underserved. 2009;20:780-797.	Non-UK study
Fenech G, Thomson G. Tormented by ghosts from their past': a meta-synthesis to explore the psychosocial implications of a traumatic birth on maternal well-being. Midwifery. 2014;30:185-193.	Systematic review with no new useable data
Fenwick J, Gamble J, Creedy D, Barclay L, Buist A, Ryding EL. Women's perceptions of emotional support following childbirth: a qualitative investigation. Midwifery. 2013;29:217-224.	Non-UK study
Ferszt GG, Erickson-Owens DA. Development of an educational/support group for pregnant women in prison. Journal of Forensic Nursing. 2008;4:55-60.	Non-UK study
Finney Lamb CE, Boers M, Owens A, Copeland J, Sultana T. Exploring experiences and attitudes about health care complaints among pregnant women, mothers and staff at an opioid treatment service. Australian	Non-UK study

Health Review. 2008;32:66-75.	
Flynn HA, Henshaw E, O'Mahen H, Forman J. Patient perspectives on improving the depression referral processes in obstetrics settings: a qualitative study. General Hospital Psychiatry. 2010;32:9-16.	Non-UK study
Fung K, Dennis CL. Postpartum depression among immigrant women. Current Opinion in Psychiatry. 2010;23:342-348.	Non-systematic review
Furber CM, Garrod D, Maloney E, Lovell K, McGowan L. A qualitative study of mild to moderate psychological distress during pregnancy. International Journal of Nursing Studies. 2009;46:669-677.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Furuta M, Sandall J, Bick D. Women's perceptions and experiences of severe maternal morbidity – A synthesis of qualitative studies using a meta-ethnographic approach. Midwifery. 2014;30:158-169.	Systematic review with no new useable data
Gamble J, Creedy D, Moyle W. Counselling processes to address psychological distress following childbirth: perceptions of women. Australian Midwifery. 2004;17:12-15.	Non-UK study
Geller PA, Psaros C, Levine Kornfield S. Satisfaction with pregnancy loss aftercare: are women getting what they want? Archives of Women's Mental Health. 2010;13:111-124.	Systematic review with no new useable data
Glaser A, Bucher HU, Moergeli H, Fauchère JC, Buechi S. Loss of a preterm infant: psychological aspects in parents. Swiss Medical Weekly. 2007;137:392-401.	Non-UK study
Griffith LB. Practitioners, postnatal depression, and translation: an investigation into the representation of Bangladeshi mothers in the East End. Anthropology and Medicine. 2009;16:267-278.	Case study methodology
Haga SM, Lynne A, Slinning K, Kraft P. A qualitative study of depressive symptoms and well-being among first-time mothers. Scandinavian Journal of Caring Sciences. 2012;26:458-466.	Non-UK study
Halvorsen L, Nerum H, Øian P, Sørlie T. Giving birth with rape in one's past: a qualitative study. Birth. 2013;40:182-191.	Non-UK study
Harris DL, Daniluk JC. The experience of spontaneous pregnancy loss for infertile women who have conceived through assisted reproduction technology. Human Reproduction. 2010;25:714-720.	Non-UK study
Hauck Y, Rock D, Jackiewicz T, Jablensky A. Healthy babies for mothers with serious mental illness: a case management framework for mental health clinicians. International Journal of Mental Health Nursing. 2008;17:383-391.	Non-UK study
Henshaw EJ, Flynn HA, Himle JA, O'Mahen HA, Forman J, Fedock G. Patient preferences for clinician interactional style in treatment of perinatal depression. Qualitative Health Research. 2011;21:936-951.	Non-UK study
Hines L. The treatment views and recommendations of substance abusing women: a meta-synthesis. Qualitative Social Work: Research and Practice. 2013;12:473-489.	Systematic review with no new useable data
Holopainen D. The experience of seeking help for postnatal depression. Australian Journal of Advanced Nursing. 2002;19:39-44.	Non-UK study
Homewood E, Tweed A, Cree M, Crossley J. Becoming occluded: the transition to motherhood of women with postnatal depression. Qualitative Research in Psychology. 2009;6:313-329.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Humphries ML, Korfmacher J. The good, the bad, and the ambivalent: quality of alliance in a support program for young mothers. Infant Mental Health Journal. 2012;33:22-33.	Non-UK study

Jessup MA, Brindis CD. Issues in reproductive health and empowerment in perinatal women with substance use disorders. Journal of Addictions Nursing. 2005;16:97-105.	Non-UK study
Jevitt CM, Groer MW, Crist NF, Gonzalez L, Wagner VD. Postpartum stressors: a content analysis. Issues in Mental Health Nursing. 2012;33:309-318.	Non-UK study
Judd F, Stafford L, Gibson P, Ahrens J. The Early Motherhood Service: an acceptable and accessible perinatal mental health service. Australasian Psychiatry. 2011;19:240-246.	Non-UK study
Kelley MC, Trinidad SB. Silent loss and the clinical encounter: parents' and physicians' experiences of stillbirth-a qualitative analysis. BMC Pregnancy and Childbirth. 2012;12:137.	Non-UK study
Khalifeh H, Murgatroyd C, Freeman MP, Johnson S. Home treatment as an alternative to hospital admission for mothers in a mental health crisis: a qualitative study. Psychiatric Services. 2009;60:634–639.	Experience of care greater than one year into the postnatal period
Knudson-Martin C, Silverstein R. Suffering in silence: a qualitative meta-data-analysis of postpartum depression. Journal of Marital and Family Therapy. 2009;35:145-158.	Systematic review with no new useable data
Kuo C, Schonbrun YC, Zlotnick C, Bates N, Todorova R, Kao JC, et al. A qualitative study of treatment needs among pregnant and postpartum women with substance use and depression. Substance Use and Misuse. 2013;48:1498-1508.	Non-UK study
Lam E, Wittkowski A, Fox JRE. A qualitative study of the postpartum experience of Chinese women living in England. Journal of Reproductive and Infant Psychology. 2012;30:105-119.	Not mental health-focused
Lara-Cinisomo S, Beckjord EB, Keyser DJ. Mothers' perspectives on enhancing consumer engagement in behavioral health treatment for maternal depression. Research in the Sociology of Health Care. 2010;28:249-268.	Non-UK study
Lasiuk GC, Comeau T, Newburn-Cook C. Unexpected: an interpretive description of parental traumas' associated with preterm birth. BMC Pregnancy and Childbirth. 2013;13(Suppl. 1):S13.	Non-UK study
Leigh B, Milgrom J. Acceptability of antenatal screening for depression in routine antenatal care. Australian Journal of Advanced Nursing. 2007;24:14-18.	Non-UK study
Little L, Lowkes E. Critical issues in the care of pregnant women with eating disorders and the impact of their children. Journal of Midwifery and Women's Health. 2000;45:301-307.	Non-UK study
Logsdon MC, Pinto Foltz M, Stein B, Usui W, Josephson A. Adapting and testing telephone-based depression care management intervention for adolescent mothers. Archives of Women's Mental Health. 2010;13:307-317.	Non-UK study
Lutz KF. Abused pregnant women's interactions with health care providers during the childbearing year. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2005;34:151-162.	Non-UK study
Lyberg A, Severinsson E. Fear of childbirth: mothers' experiences of team-midwifery care – a follow-up study. Journal of Nursing Management. 2010;18:383-390.	Non-UK study
Mason WA, Rice MJ, Records K. The lived experience of postpartum depression in a psychiatric population. Perspectives in Psychiatric Care. 2005;41:52-61.	Non-UK study
Maxwell A, Proctor J, Hammond L. 'Me and my child': parenting	Not mental health-focused

experiences of young mothers leaving care. Adoption and Fostering. 2011;35:29-40.	
McCarthy M, McMahon C. Acceptance and experience of treatment for postnatal depression in a community mental health setting. Health Care for Women International. 2008;29:618-637.	Non-UK study
McComish JF, Groh CJ, Moldenhauer JA. Development of a doula intervention for postpartum depressive symptoms: participants' recommendations. Journal of Child and Adolescent Psychiatric Nursing. 2013;26:3-15.	Non-UK study
McCourt C, Pearce A. Does continuity of care matter to women from minority ethnic groups? Midwifery. 2000;16:145–154.	Not mental health-focused
McLeish J. Maternity experiences of asylum seekers in England. British Journal of Midwifery. 2005;13:782-785.	Not mental health-focused
Modiba L, Nolte AGW. The experiences of mothers who lost a baby during pregnancy. Health SA Gesondheid. 2007;12:3-13.	Non-UK study
Montgomery P, Tompkins C, Forchuk C, French S. Keeping close: mothering with serious mental illness. Journal of Advanced Nursing. 2006;54:20–28.	Non-UK study
Montgomery P, Mossey S, Bailey P, Forchuk C. Mothers with serious mental illness: their experience of "hitting bottom". ISRN Nursing. 2011;2011:708318.	Non-UK study
Montgomery E. Feeling safe: a metasynthesis of the maternity care needs of women who were sexually abused in childhood. Birth. 2013;40:88-95.	Systematic review with no new useable data
Mulder E, Davis A, Gawley L, Bowen A, Einarson A. Negative impact of non-evidence-based information received by women taking antidepressants during pregnancy from health care providers and others. Journal of Obstetrics and Gynaecology Canada. 2012;34:66-71.	Non-UK study
Murphy S. Reclaiming a moral identity: stillbirth, stigma and 'moral mothers'. Midwifery. 2012;28:476-480.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Muzik M, Ads M, Bonham C, Rosenblum KL, Broderick A, Kirk R. Perspectives on trauma-informed care from mothers with a history of childhood maltreatment: a qualitative study. Child Abuse and Neglect. 2013;37:1215-1224.	Non-UK study
Napravnik S, Royce R, Walter E, Lim W. HIV-1 infected women and prenatal care utilization: barriers and facilitators. AIDS Patient Care and STDs. 2000;14:411-420.	Non-UK study
Neale A, Wand A. Issues in the evaluation and treatment of anxiety and depression in migrant women in the perinatal period. Australasian Psychiatry. 2013;21:379-382.	Systematic review with no new useable data
Nolan ML, Mason V, Snow S, Messenger W, Catling J, Upton P. Making friends at antenatal classes: a qualitative exploration of friendship across the transition to motherhood. Journal of Perinatal Education. 2012;21:178-185.	Not mental health-focused
Nordlund E, Börjesson A, Cacciatore J, Pappas C, Randers I, Rådestad I. When a baby dies: motherhood, psychosocial care and negative affect. British Journal of Midwifery. 2012;20:780-784.	Non-UK study
Nottage SL. Parents' use of nonmedical support services in the neonatal intensive care unit. Issues in Comprehensive Pediatric Nursing. 2005;28:257-273.	Non-UK study

Novick G, Sadler LS, Knafl KA, Groce NE, Kennedy HP. The intersection of everyday life and group prenatal care for women in two urban clinics. Journal of Health Care for the Poor and Underserved. 2012;23:589-603.	Non-UK study
Nystrom K, Axelsson K. Mothers' experience of being separated from their newborns. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2002;31:275-282.	Non-UK study
Oates MR, Cox JL, Neema S, Asten P, Glangeaud-Freudenthal N, Figueiredo B, et al. Postnatal depression across countries and cultures: a qualitative study. British Journal of Psychiatry. 2004;184:s10-16.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Obeidat HM, Bond EA, Callister LC. The parental experience of having an infant in the newborn intensive care unit. Journal of Perinatal Education. 2009;18:23-29.	Systematic review with no new useable data
Ogden J, Maker C. Expectant or surgical management of miscarriage: a qualitative study. BJOG. 2004;111:463-467.	Not mental health-focused
O'Mahen H, Fedock G, Henshaw E, Himle JA, Forman J, Flynn HA. Modifying CBT for perinatal depression: what do women want?: a qualitative study. Cognitive and Behavioral Practice. 2012;19:359-371.	Non-UK study
O'Mahony JM, Donnelly TT, Bouchal SR, Este D. Barriers and facilitators of social supports for immigrant and refugee women coping with postpartum depression. Advances in Nursing Science. 2012a;35:E42-E56.	Non-UK study
O'Mahony, JM, Donnelly TT, Este D, Bouchal SR. Using critical ethnography to explore issues among immigrant and refugee women seeking help for postpartum depression. Issues in Mental Health Nursing. 2012b;33:735-742.	Non-UK study
Peay HL, Hooker GW, Kassem L, Biesecker BB. Family risk and related education and counseling needs: perceptions of adults with bipolar disorder and siblings of adults with bipolar disorder. American Journal of Medical Genetics Part A. 2009;149A:364–371.	Non-UK study
Poole H, Mason L, Osborn T. Women's views of being screened for postnatal depression. Community Practitioner. 2006;79:363-367.	Paper unavailable
Pursley-Crotteau S. Perinatal crack users becoming temperant: the social psychological processes. Health Care for Women International. 2001;22:49-66.	Non-UK study
Ramvi E, Tangerud M. Experiences of women who have a vaginal birth after requesting a cesarean section due to a fear of birth: a biographical, narrative, interpretative study. Nursing and Health Sciences. 2011;13:269-274.	Non-UK study
Renker PR. "Keep a blank face. I need to tell you what has been happening to me." Teens' stories of abuse and violence before and during pregnancy. American Journal of Maternal Child Nursing. 2002;27:109-116.	Non-UK study
Reynolds S. Postpartum psychiatric illness: can women recognise the onset? RCM Midwives. 2005;8:342-345.	Paper unavailable
Rose L, Alhusen J, Bhandari S, Soeken K, Marcantonio K, Bullock L, et al. Impact of intimate partner violence on pregnant women's mental health: mental distress and mental strength. Issues in Mental Health Nursing. 2010;31:103-111.	Non-UK study
Roseth I, Binder P-E, Malt UF. Two ways of living through postpartum depression. Journal of Phenomenological Psychology. 2011;42:174-194.	Experience of disorder with no explicit implications for management, planning

	and/or delivery of care
Ross LE, Siegel A, Dobinson C, Epstein R, Steele LS. "I don't want to turn totally invisible": mental health, stressors, and supports among bisexual women during the perinatal period. Journal of GLBT Family Studies. 2012;8:137-154.	Non-UK study
Rossiter C, Fowler C, McMahon C, Kowalenko N. Supporting depressed mothers at home: their views on an innovative relationship-based intervention. Contemporary Nurse. 2012;41:90-100.	Non-UK study
Rothera I, Oates M. Managing perinatal mental health disorders effectively: identifying the necessary components of service provision and delivery. Psychiatric Bulletin. 2008;32:131-133.	Mixed professional and service user respondents, and not possible to extract disaggregated service user data
Rowe HJ, Holton S, Fisher JRW. Postpartum emotional support: a qualitative study of women's and men's anticipated needs and preferred sources. Australian Journal of Primary Health. 2013;19:46-52.	Non-UK study
Ryding EL, Wijma K, Wijma B. Emergency cesarean section: 25 women's experiences. Journal of Reproductive and Infant Psychology. 2000;18:33-39.	Non-UK study
Sahlin M, Carlander-Klint AK, Hildingsson I, Wiklund I. First-time mothers' wish for a planned caesarean section: deeply rooted emotions. Midwifery. 2013;29:447-452.	Non-UK study
Schenk LK, Kelley JH. Mothering an extremely low birth-weight infant: a phenomenological study. Advances in Neonatal Care. 2010;10:88-97.	Non-UK study
Scope A, Booth A, Sutcliffe P. Women's perceptions and experiences of group cognitive behaviour therapy and other group interventions for postnatal depression: a qualitative synthesis. Journal of Advanced Nursing. 2012;68:1909-1919.	Systematic review with no new useable data
Scrandis DA. Normalizing postpartum depressive symptoms with social support. Journal of the American Psychiatric Nurses Association. 2005;11:223-230.	Non-UK study
Seng JS, Sparbel KJ, Low LK, Killion C. Abuse-related posttraumatic stress and desired maternity care practices: women's perspectives. Journal of Midwifery and Women's Health. 2002;47:360-370.	Non-UK study
Shakespeare J, Blake F, Garcia J. Breast-feeding difficulties experienced by women taking part in a qualitative interview study of postnatal depression. Midwifery. 2004;20:251-260.	Not mental health-focused
Shanok AF, Miller L. Depression and treatment with inner city pregnant and parenting teens. Archives of Women's Mental Health. 2007;10:199-210.	Non-UK study
Smith VC, Steelfisher GK, Salhi C, Shen LY. Coping with the neonatal intensive care unit experience: parents' strategies and views of staff support. Journal of Perinatal and Neonatal Nursing. 2012;26:343-352.	Non-UK study
Soderstrom K. Mental preparation during pregnancy in women with substance addiction: a qualitative interview-study. Child and Family Social Work. 2012;17:458-467.	Non-UK study
Sterling BS, Fowles ER, Garcia AA, Jenkins SK, Wilkinson S, Kim M, et al. Altered perceptions of personal control about retained weight and depressive symptoms in low-income postpartum women. Journal of Community Health Nursing. 2009;26:143-157.	Non-UK study
Stevens J, Ammerman RT, Putnam FW, Gannon T, Van Ginkel JB. Facilitators and barriers to engagement in home visitation: a qualitative	Non-UK study

analysis of maternal, provider, and supervisor data. Journal of Aggression, Maltreatment and Trauma. 2005;11:75-93.	
Straus L, McEwen A, Hussein M. Somali women's experience of childbirth in the UK: perspectives from Somali health workers. Midwifery. 2009;25:181–186.	Not mental health-focused
Sword W, Niccols A, Fan A. "New choices" for women with addictions: perceptions of program participants. BMC Public Health. 2004;4:10.	Non-UK study
Sword W, Busser D, Ganann R, McMillan T, Swinton M. Women's care-seeking experiences after referral for postpartum depression. Qualitative Health Research. 2008;18:1161-1173.	Non-UK study
Tabb KM, Gavin AR, Guo Y, Huang H, Debiec K, Katon W. Views and experiences of suicidal ideation during pregnancy and the postpartum: findings from interviews with maternal care clinic patients. Women and Health. 2013;53:519-535.	Non-UK study
Tamaki A. Effectiveness of home visits by mental health nurses for Japanese women with post-partum depression. International Journal of Mental Health Nursing. 2008;17:419-427.	Non-UK study
Tammentie T, Paavilainen E, Tarkka MT, Astedt-Kurki P. Families' experiences of interaction with the public health nurse at the child health clinic in connection with mother's post-natal depression. Journal of Psychiatric and Mental Health Nursing. 2009;16:716-724.	Non-UK study
Tham V, Ryding EL, Christensson K. Experience of support among mothers with and without post-traumatic stress symptoms following emergency caesarean section. Sexual and Reproductive Healthcare. 2010;1:175-180.	Non-UK study
Tierney S, Fox JR, Butterfield C, Stringer E, Furber C. Treading the tightrope between motherhood and an eating disorder: a qualitative study. International Journal of Nursing Studies. 2011;48:1223-1233.	Experience of disorder with no explicit implications for management, planning and/or delivery of care
Tierney S, McGlone C, Furber C. What can qualitative studies tell us about the experiences of women who are pregnant that have an eating disorder? Midwifery. 2013;29:542-549.	Systematic review with no new useable data
Trulsson O, Radestad I. The silent child – mothers' experiences before, during, and after stillbirth. Birth. 2004;31:189-195.	Non-UK study
Ugarriza DN. Postpartum depressed women's explanation of depression. Journal of Nursing Scholarship. 2002;34:227-233.	Non-UK study
Ugarriza DN. Group therapy and its barriers for women suffering from postpartum depression. Archives of Psychiatric Nursing. 2004;18:39-48.	Non-UK study
Venkataraman M, Ackerson BJ. Parenting among mothers with bipolar disorder: strengths, challenges, and service needs. Journal of Family Social Work. 2008;11:389–408.	Non-UK study
Wardrop AA, Popadiuk NE. Women's experiences with postpartum anxiety: expectations, relationships, and sociocultural influences. Qualitative Report. 2013;18:1-24.	Non-UK study
Wheatley SL, Brugha TS, Shapiro DA. Exploring and enhancing engagement to the psychosocial intervention 'Preparing for Parenthood'. Archives of Women's Mental Health. 2003;6:275-285.	Not mental health-focused
Wickberg B, Hwang CP. Counselling of postnatal depression: a controlled study on a population-based Swedish sample. Journal of Affective Disorders. 1996;39:209-216.	Non-UK study
Williams P. Mothers' descriptions of recovery from postpartum depression. American Journal of Maternal Child Nursing. 2013;38:276-	Non-UK study

281.	
Wilson L, Crowe M. Parenting with a diagnosis bipolar disorder. Journal of Advanced Nursing. 2009;65:877–884.	Non-UK study
Woolhouse H, Brown S, Krastev A, Perlen S, Gunn J. Seeking help for anxiety and depression after childbirth: Results of the Maternal Health Study. Archives of Women's Mental Health. 2009;12:75-83.	Non-UK study

1.5 PSYCHOSOCIAL INTERVENTIONS: PREVENTION (RISK FACTORS IDENTIFIED) – INCLUDED STUDIES

1.5.1 ARACENA2009

Study ID	ARACENA2009
Bibliographic reference	Aracena M, Krause M, Pérez C, Méndez MJ, Salvatierra L, Soto M, et al. A cost-effectiveness evaluation of a home visit program for adolescent mothers. Journal of Health Psychology. 2009;14: 878-887.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Not reported **Setting:** Home **Country:** Chile
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Unclear (Goldberg's Questionnaire, at the beginning of the intervention experimental group rated an average of 11.30 points on the mental health scale [SD=5.56]. control group had an average score of 12.63 points [sd 5.55]) **N (number randomised):** 104 **Mean age (years):** 17.21 **Risk factor/s:** Adolescence and Psychosocial (living in an extremely poor neighborhood) risk factors **Inclusion criteria:** i) being pregnant for the first time and aged 14-19 years old; ii) living in an extremely poor neighborhood of Santiago de Chile. **Exclusion criteria:** i) being over 20 years of age at the first prenatal check-up at the health center; ii) being married at the time of the first prenatal check-up at the health center; iii) having some chronic health problem (like epilepsy or mental retardation).
Interventions	**Experimental intervention** **Name:** Home visiting **Description:** The program sought to: (1) encourage the young woman's development of her identity as a woman, adolescent, and mother; (2) help her develop life plans; (3) reinforce her parenting skills; (4) promote basic health care practices for both mother andchild; and (5) strengthen the adolescent's relationships with those around her. Materials included the Educator's Manual, which addresses the various topics: adolescence, identity, self esteem and life plans, caring for one's own body, child care, child development, and problem-solving skills. **Format:** Individual **Group size:** Not applicable **Sessions:** 12 **Frequency (number of doses per week):** 0.23 **Duration (weeks):** Not reported **Provider:** Health educators under the guidance of nurse-midwives **Control intervention** **Name:** Treatment as usual **Description:** Standard prenatal and well-baby care at the local health centers **Format:** Individual **Group size:** N/A

	Sessions: 10 **Frequency (number of doses per week):** 0.19 **Duration (weeks):** Not reported **Provider:** Nurse midwife
Outcomes	**Outcomes used:** Maternal mental health (Goldberg's General Health Questionnaire); Infant's physical health (weight and incidence of severe diarrhoea as ascertained from health centre medical records); Infant psychomotor skills (Psychomotor Development Scale [Escala de Desarrollo Psicomotor, EEDP]); Indicators for child abuse (evaluations completed by hea;th centre's social workers) **Outcomes not used:** Maternal physical health; Child illnesses with exception of diarrhoea could not be extracted; Data for subscales for infant psychomotor development could not be extracted
Study design	Randomised controlled trial (RCT)
Source of funding	Chiles National Fund for Science and Technology
Limitations	1. Risk of selection bias is unclear/unknown as the method if randomisation is unclear and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of detection blinding is unclear/unknown as identity and blinding of outcome assessor/s is not reported 4. Risk of bias with analysis method as data reported is available case and ITT cannot be computed as number randomised into each group not reported 5. Risk of selective reporting bias is unclear/unknown
Notes	Data requested for, and author response pending for: 1) Number of participants initially randomised to groups before dropout; 2) Mean and standard deviations for all outcomes at all time points; 3) Details of randomisation

1.5.2 BARLOW2007

Study ID	BARLOW2007
Bibliographic reference	Barlow J, Davis H, McIntosh E, Jarrett P, Mockford C, Stewart-Brown S. Role of home visiting in improving parenting and health in families at risk of abuse and neglect: results of a multicentre randomised controlled trial and economic evaluation. Archives of Disease in Childhood. 2007;92: 229-233.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded (data were collected, coded and analysed by researchers who had not been involved in recruitment and were therefore blind to the intervention group) **Setting:** Home **Country:** UK
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 18% >=8 risk factors **N (number randomised):** 131

	Mean age (years): Not reported **Risk factor/s:** Psychosocial and (family) history of mental health problems risk factors (mean number of risk factors per woman was five) **Inclusion criteria:** i) screened using a range of demographic and socioeconomic criteria (eg, mental health problems or housing problems) **Exclusion criteria:** i) Women not wishing to be randomised; ii) without a working understanding of English.
Interventions	**Experimental intervention** **Name:** Family Nurse Partnership **Description:** All parents randomised to the intervention group received 18 months of weekly visits from a health visitor trained in understanding the processes of helping, skills of relating toparents effectively and methods of promoting parent–infantinteraction using the Family Partnership Model **Format:** Individual **Group size:** Not applicable **Sessions:** 41 **Frequency (number of doses per week):** 1 **Duration (weeks):** 78 **Provider:** Health visitor **Control intervention** **Name:** Treatment as usual **Description:** Standard help currently available to such families **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** N/A **Duration (weeks):** 78 **Provider:** Not reported
Outcomes	**Outcomes used:** Maternal sensitivity and infant cooperativeness (behavioural observation coded using CARE index); General mental health (GHQ); Social support (Social Support Questionnaire); Self-Esteem (Rosenberg Self-Esteem Inventory) **Outcomes not used:** Data not reported for EPDS or Parental stress (PSI) or infant-toddler social and emtoional adjustment (Brief Infant-Toddler Social and Emotional Assessment) or infant development (Bayley Scales of Infant Development) or Maternal assessment of infant temperament (ITS). Other outcomes not used as outside scope: Parenting attitudes and competence (Adult Adolescent Parenting Inventory, Parenting Sense of Competence scale, WBPB); Marital/partner discord (Rust Inventory of Marital State); Perceived self-efficacy (Generalised Self-Efficacy Scale)
Study design	Randomised controlled trial (RCT)
Source of funding	Department of Health, Nuffield Foundation.
Limitations	1. Risk of selection bias is unclear/unknown as the method if randomisation is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data not provided for multiple outcomes including Edinburgh Postnatal Depression Scale (EPDS); Parenting Stress Index (PSI); Brief Infant–Toddler Social and Emotional Assessment; Bayley Scales of Infant Development
Notes	Data requested for, and author response pending for: Mean and standard

	deviations of all outcome measures at all time points including: Edinburgh Postnatal Depression Scale (EPDS); Parenting Stress Index (PSI); Brief Infant–Toddler Social and Emotional Assessment; Bayley Scales of Infant Development

1.5.3 BARNET2007

Study ID	BARNET2007
Bibliographic reference	Barnet B, Liu J, DeVoe M, Alperovitz-Bichell K, Duggan AK. Home visiting for adolescent mothers: effects on parenting, maternal life course, and primary care linkage. Annals of Family Medicine. 2007;5: 224-232.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 34.5% CES-D score >21 **N (number randomised):** 84 **Mean age (years):** 16.9 **Risk factor/s:** Adolescence and Psychosocial (economically disadvantaged) risk factors **Inclusion criteria:** i) pregnant adolescents aged 12 to 18 years; ii) pregnancies were of least 24 weeks' gestation; ii) attending one of three urban, university-affiliated prenatal care sites in Baltimore, Md. **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Home visitation, mentoring, and case management **Description:** Home visitors delivered a parenting curriculum and an adolescent curriculum.The parenting curriculum sessions aimed to improve teens' understanding of child development, teach and model good parenting attitudes and skills, and promote appropriate health care use. The adolescent curriculum sessions provided skills-based, interactive instruction on safer sexual practices, prevention of repeat pregnancy, goal setting geared toward school completion, and training geared toward improving communication and negotiation with partners. **Format:** Individual **Group size:** Not applicable **Sessions:** 45 **Frequency (number of doses per week):** 0.5 in first year/0.25 in second year **Duration (weeks):** 117 **Provider:** Trained African American women who were recruited from communities served by the program **Control intervention** **Name:** Treatment as usual **Description:** Usual care **Format:** Individual **Group size:** N/A **Sessions:** Not reported

	Frequency (number of doses per week): Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression (CES-D score >=21); Service utilisation (has a regular personal doctor at year 2) **Outcomes not used:** Contraception use; Repeat pregnancy /birth; school status; parenting attitudes and beliefs (Bavolek's Adult Adolescent Parenting Inventory [AAPI])
Study design	Randomised controlled trial (RCT)
Source of funding	Office of AdolescentPregnancy Programs, Department of Health and Human Services, grantAPHPA0002011
Limitations	1. High risk of selection bias as method if randomisation and allocation concealment is unclear and there were statistically significant group difference at baseline (intervention group scored higher on measure of parenting attitudes and beliefs) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	Data requested for, and author response pending for: Details of method of randomisation, including sequence generation and allocation concealment

1.5.4 BRUGHA2000

Study ID	BRUGHA2000
Bibliographic reference	Brugha TS, Wheatley S, Taub NA, Culverwell A, Friedman T, Kirwan P, et al. Pragmatic randomized trial of antenatal intervention to prevent post-natal depression by reducing psychosocial risk factors. Psychological Medicine. 2000;30: 1273-1281.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report and blinded outcome assessment **Setting:** Hospital **Country:** UK
Participants	**Timing:** Antenatal **Baseline symptoms:** 22-23% scored 'high' (=>3) on the GHQ-D **N (number randomised):** 209 **Mean age (years):** 19 (median) **Risk factor/s:** Psychosocial risk factors (83-84% low [<=5] social support) **Inclusion criteria:** i) at least 16 years of age at booking for obstetric care; ii) in a First pregnancy that she planned to continue to full-term; iii) residing within reasonable travelling distance of the hospital; iv) capable of understanding and completing screening questionnaires in English and of giving written, informed consent **Exclusion criteria:** i) advanced gestation preventing full participation
Interventions	**Experimental intervention** **Name:** Preparing for Parenthood (PFP) **Description:** PFP uses cognitive and problem solving approaches together with emerging models for enhancing social support at an individual level.

	Each group included three or four exercises in which women were encouraged to share and discuss principles and topics using personal examples of their own. There were two role-plays. A problem-solving model and other key constructive behaviours were reinforced regularly and women were encouraged to practice new skills between sessions. Key elements included: Acknowledgement and discussion of social and emotional problems of pregnancy; Information about postnatal depression, its identification, sources of help and the importance of social support; Learning ways to develop, use and maintain support skills;Learning and practising problem solving skills, especially in relation to risk factors; Identification and exploration of unhelpful thoughts and beliefs about pregnancy and motherhood **Format:** Group **Group size:** 8-16 **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Nurses and occupational therapists **Control intervention** **Name:** Treatment as usual **Description:** Routine antenatal care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 6 **Provider:** Not reported
Outcomes	**Outcomes used:** EPDS = >11; SCAN ICD-10 F32/F33 diagnosis; Social support; Service utilisation; Drop-out **Outcomes not used:** GHQ-D=>2 (because EPDS also reported and this is more widely used measure of depression symptomatology); Problem solving; Locus of control; Life events; Activities of daily living (ADL); Satisfaction with housing
Study design	Randomised controlled trial (RCT)
Source of funding	The National Health Service Research and DevelopmentNational Mental Health Programme andLeicestershire Mental Health Services NHS Trust
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.5.5 COOPER2009

Study ID	COOPER2009
Bibliographic reference	Cooper PJ, Tomlinson M, Swartz L, Landman M, Molteno C, Stein A, et al. Improving quality of mother-infant relationship and infant attachment in socioeconomically deprived community in South Africa: randomised controlled trial. BMJ. 2009;338: b974.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants)

	Blinding of personnel: Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report and blinded outcome assessment **Setting:** Home **Country:** South Africa
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Without diagnosis **N (number randomised):** 449 **Mean age (years):** 25.9 **Risk factor/s:** Psychosocial risk factors (women living in socioeconomically deprived community in South Africa) **Inclusion criteria:** Pregnant women living in the prespecified area **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Relationship/ attachment based intervention **Description: I**ntervention based on an adaptation of a preventative intervention programme by health visitors devised for implementation in Britain, which itself closely follows the principles of The Social Baby (Murray & Andrews, 2002. The aim was to encourage the mother in sensitive, reponsive interactions with her infant. A major aspect was the use of particular items from the neonatal behavioural assessment schedule, to sensitise the mother to her infant's individual capacities and needs **Format:** Individual **Group size:** N/A **Sessions: 1**6 **Frequency (number of doses per week):** Variable (twice antenatally; weekly for the first 8 weeks postpartum; fortnighly for a further two months; then monthly for two months) **Duration (weeks):** Not reported (ending at 5 months postpartum) **Provider:** Trained volunteers who were mothers themselves **Control intervention** **Name:** Treatment as usual **Description:** Normal service provided by the local infant clinic (as did the intervention group). Communtiy health worker assessed the physical and medical progress of the mother and infnat, and encouraged the mother to take their infant to the local clinic to b weighed, have physcial health assessed, and be immunised **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** 0.5 **Duration (weeks):** Not reported **Provider:** Comunity health worker
Outcomes	**Outcomes used:** Depression diagnosis (DSM-IV); Depression symptoms (EPDS); Infant attachment (Ainsworth Strange Situation Procedure); Drop-out **Outcomes not used:** Data cannot be extracted for maternal sensitivity and intrusiveness as Ns not reported; Data not extracted for Secure subscale of Ainsworth Strange Situation Procedure as Insecure extracted to be consistent with other studies with scales where lower is better; Data not included in meta-analysis for subscales of Ainsworth Insecure (Avoidant, Resistant, Disorganised)
Study design	Randomised controlled trial (RCT)

Source of funding	Grant (B574100) from theWellcome Trust. MT was supported by a fellowship from the VlotmanTrust.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear/unknown as paper reports available case analysis and although ITT (WCS) computed wherever possible this could not be computed for all outcome measures
Notes	Protocol registered: ISRCTN25664149.

1.5.6 EASTERBROOKS2013

Study ID	EASTERBROOKS2013
Bibliographic reference	Easterbrooks MA, Bartlett JD, Raskin M, Goldberg J, Contreras MM, Kotake C. Limiting home visiting effects: maternal depression as a moderator of child maltreatment. Pediatrics. 2013;132 (Suppl. 2): S126-S133.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** 37% of sample had CES-D scores>16. Baseline CES-D mean: 14.3 (SD 7.1) **N (number randomised):** 707 **Mean age (years):** 18.7 **Risk factor/s:** Adolescence and Psychosocial (57.8% mothers were welfare recipients) risk factors **Inclusion criteria:** i) First-time mothers; ii) at least 16 years of age; iii) having received no Healthy Families Massachusetts (HFM) services in the past; iv) speaking English or Spanish; v) being cognitively able to provide informed consent **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Healthy Families Massachusetts **Description:** Healthy Families Massachusetts (HFA) intervention is a statewide paraprofessional home visiting programme for adolescent first-time mothers and is aimed at: preventing child abuse and neglect by supporting positive, effective parenting; promoting optimal health, growth, and development in infancy and early childhood; encouraging educational attainment, job, and life skills among parents; preventing repeat pregnancies during the teenage years; and promoting parental health and wellbeing. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Paraprofessional **Control intervention**

	Name: Treatment as usual **Description:** Mothers in the control group were referred to other service providers **Format:** N/A **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** Not reported **Provider:** N/A
Outcomes	**Outcomes used:** Depression symptomatology (CES-D>16); Depresison mean scores (CES-D) **Outcomes not used:** Data cannot be extracted for child abuse and neglect (primary outcome) as data is not split by group and data not reported for 24 month follow-up
Study design	Randomised controlled trial (RCT)
Source of funding	Massachusetts Children's Trust Fund; Pew Center for the States
Limitations	1. High risk of selection bias as randomisation method and allocation concealment is unclear and statistically significant baseline group differences in mean depression scores [mean CES-D=13.37 in intervention group and 15.72 in control group] and baseline depression symptomatology [34% CES-D>16 in intervention group and 43% in control group] and in ethnicity [with a higher percentage of Hispanic mothers in the intervention group]) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with analysis method as although paper states that ITT analysis conducted the data were indicative of an available case analysis and not possible to compute ITT (WCS) due to unclear group Ns at baseline 4. High risk of selective reporting bias as data cannot be extracted for child abuse and neglect (primary outcome) and data is not split by group and data not reported for 24 month follow-up 5. Risk of attrition bias is unclear as unclear group Ns at baseline
Notes	Protocol registered: NCT01926223

1.5.7 GORMAN1997/DENIIS2013

Study ID	GORMAN1997/DENNIS2013
Bibliographic reference	Gorman L. Prevention of postpartum difficulties in a high risk sample [dissertation]. Iowa City (IA): University of Iowa; 1997. Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. Cochrane Database of Systematic Reviews. 2013;2: CD001134.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Not reported

	Country: US
Participants	**Timing:** Antenatal **Baseline symptoms:** Unclear **N (number randomised):** 45 **Mean age (years):** Not reported **Risk factor/s:** Unclear ('at-risk') **Inclusion criteria:** Not reported **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** IPT **Description:** Individual sessions based on interpersonal psychotherapy (no other detail accessible) **Format:** Individual **Group size:** N/A **Sessions:** 5 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** PhD psychology student **Control intervention** **Name:** Treatment as usual **Description:** Standard care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression (EPDS>12 and SCID) **Outcomes not used:** Unclear
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method was unclear as data reported in DENNIS2013 is available case and although ITT (WCS) was computed wherever possible this was not possible for all outcome measures 3. Risk of selective reporting bias was unclear 4. Risk of attrition bias was unclear
Notes	Could not access the unpublished data, data extracted from DENNIS2013

1.5.8 HARRIS2006/DENIIS2013

Study ID	HARRIS2006/DENNIS2013
Bibliographic reference	Harris T, Brown GW, Hamilton V, Hodson S, Craig TKJ. The Newpin antenatal and postnatal project: a randomised controlled trial of an intervention for perinatal depression. HSR Open Day; 6 July 2006; Institute of Psychiatry, Kings College London.

	Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. Cochrane Database of Systematic Reviews. 2013;2: CD001134.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Non-blind **Setting:** Not reported **Country:** UK
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Unclear **N (number randomised):** 117 **Mean age (years):** Not reported **Risk factor/s:** Unclear ('at-risk') **Inclusion criteria:** i) women at risk for depression ii) no psychotic illness or serious suicidal risk iii) good fluency in English **Exclusion criteria:** Diagnosis of major depression at baseline
Interventions	**Experimental intervention** **Name:** NEWPIN (New Parent Infant Network) program **Description:** The NEWPIN program provides antenatal and postnatal social support with 1-to-1 befriending and psychoeducational group meetings by trained volunteers who themselves are mothers **Format:** Group **Group size:** Not reported **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Trained volunteers who themselves are mothers **Control intervention** **Name:** Treatment as usual **Description:** Usual care **Format:** N/A **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Diagnosis of depression (SCAN) **Outcomes not used:** Unclear
Study design	Randomised controlled trial (RCT)
Source of funding	None acknowledged
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of detection bias due to non-blind outcome assessment 3. Risk of selective reporting bias was unclear (DENNIS2013 reports registration but could not be found) 4. Risk of attrition bias was unclear
Notes	Could not access the unpublished data, data extracted from DENNIS2013

1.5.9 HOWELL2012

Study ID	HOWELL2012
Bibliographic reference	Howell EA, Balbierz A, Wang J, Parides M, Zlotnick C, Leventhal H. Reducing postpartum depressive symptoms among black and latina mothers: a randomized controlled trial. Obstetrics and Gynecology. 2012;119: 942-949.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital and telephone **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** Mean EPDS scores at baseline = 3.35 (4.2 (4.6) intervention and 4.5 (4.9) control). N=45 (20 in intervention group and 25 in control group) had high levels of depressive symptoms at baseline (EPDS=>13, PHQ-9=>20, or suicidal ideation) **N (number randomised):** 540 **Mean age (years):** 28 **Risk factor/s:** Psychosocial risk factors **Inclusion criteria:** i) black or African American, or Latina or Hispanic, ii) aged 18 years or older, iii) had infants with birth weights of 2500 grams or higher, and 5-minute Apgar scores of 7 or greater; iv) had a working telephone **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Behavioural Educational Intervention **Description:** Patients randomized to the intervention arm were given a 2-step behavioral educational intervention. The in-hospital component of the intervention involved a 15-minute, in hospital review of a patient education pamphlet and partner summary sheet by the mother with a masters-trained bilingual social worker. The pamphlet represented each potential trigger of depressive symptoms as a “normal” aspect of the postpartum experience, and provided specific suggestions for management. The social worker reviewed the patient education pamphlet and partner summary sheet with the patient during her postpartum hospital stay and answered questions. The second step was a two-week post-delivery telephone call in which the social worker assessed patients' symptoms, skills in symptom management, and other needs. The "to do" lists to help alleviate symptoms were reviewed when needed and participant and social worker created action plans to address current needs including accessing community resources **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** 0.5 **Duration (weeks):** 2 **Provider:** Social worker **Control intervention** **Name:** EnhancedTreatment as usual **Description:** Routine postpartum hospital education, (that is, discharge materials, television educational programs on infant care, breastfeeding, and perinatal care). To ensure equivalent contact, patients assigned to enhanced usual care control received a two-week post delivery call to inform them of

	future surveys and a list of health related and community resources was mailed to them. **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** 0.5 **Duration (weeks):** 2 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS=>10) **Outcomes not used:** Data not reported for mean EPDS scores, no data from PHQ-9 reported and no medical chart data reported. Data could not be extracted for drop-out as not split by group
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute for Minority Health and Health Disparities (5P60MD000270-10) and theNational Institute for Mental Health
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias (secondary outcome measures not reported: Breastfeeding continuation rate and Physical functioning)
Notes	Protocol registered: NCT01312883

1.5.10 KERSTING2013

Study ID	KERSTING2013
Bibliographic reference	Kersting A, Dölemeyer R, Steinig J, Walter F, Kroker K, Baust K, et al. Brief internet-based intervention reduces posttraumatic stress and prolonged grief in parents after the loss of a child during pregnancy: a randomized controlled trial. Psychotherapy and Psychosomatics. 2013;82: 372–381.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Internet **Country:** European German-speaking countries
Participants	**Timing:** Post-miscarriage **Baseline symptoms:** 37% of sample had IES score>35. Baseline IES-R mean: 31.1 (SD 8.6) **N (number randomised):** 228 **Mean age (years):** 34.2 **Risk factor/s:** Miscarriage, termination due to fetal abnormality, or stillbirth **Inclusion criteria:** i) having lost a child during pregnancy because of miscarriage, termination due to medical indications, or stillbirth; ii) residence in a European German-speaking country; iii) written and oral fluency in German; iv) access to the Internet; v) age ≥ 18 years; vi) signed informed consent **Exclusion criteria:** i) severely depressed mood or suicidal ideation (SCL-90: Depression=>20; risk of suicide assessed using Suicide Risk Assessment); ii) dissociative tendency (assessed using Somatoform Dissociation Questionnaire); iii) risk of psychosis (assessed using the Dutch Screening

	Device for Psychotic Disorder); iv) current pregnancy ; v) substance abuse and dependency (assessed using the Biographical Information Questionnaire); vi) currently receiving treatment elsewhere.
Interventions	**Experimental intervention** **Name:** Brief internet-based intervention after loss of child during pregnancy **Description:** Brief internet-based intervention for parents after the loss of a child during pregnancy. The self-help intervention was based on CBT principles and participants were assigned written tasks (10 x 45-minute assigments) which were personalized by the therapist for each participant. The intervention consisted of three phases: self-confrontation (participants were instructed to write four texts addressing the circumstances of the pregnancy loss); cognitive reappraisal (participants were instructed to write a supportive and encouraging letter to a hypothetical friend who had experienced pregnancy loss which reflected on feelings of guilt, challenging dysfunctional thought and behaviour patterns and correcting unrealistic assumptions); social sharing (participants were instructed to write a letter to a signficant person/witness to loss/themselves outlining their most difficult memories of their pregnancy loss, reflecting on the therapeutic process and future plans for coping). The therapist time in responding to written assignments was 20-50 minutes per text. **Format:** Individual **Group size:** N/A **Sessions:** 0 sessions of contact with professional; 5 internet sessions (10 essays) **Frequency (number of doses per week):** 1 **Duration (weeks):** 5 **Provider:** Therapist **Control intervention** **Name:** Treatment as usual **Description:** Waitlist control group **Format:** N/A **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 5 **Provider:** N/A
Outcomes	**Outcomes used:** Drop-out; PTSD symptomatology (IES>35); PTSD mean scores (IES-R); Depression mean scores (BSI); Anxiety mean scores (BSI); General mental health (BSI) **Outcomes not used:** Data was not extracted for the Inventory of Complicated Grief (ICG)
Study design	Randomised controlled trial (RCT)
Source of funding	German Federal Ministry for Family, Seniors, Women, and Youth
Limitations	1. High risk of selection bias due to unclear allocation concealment and statistically significant difference in baseline intrusion subscale of the IES-R (19.2 in control group and 17.4 in intervention group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.5.11 KIEFFER2013

Study ID	KIEFFER2013
Bibliographic reference	Kieffer EC, Caldwell CH, Welmerink DB, Welch KB, Sinco BR, Guzmán JR. Effect of the healthy MOMs lifestyle intervention on reducing depressive symptoms among pregnant Latinas. American Journal of Community Psychology. 2013;51:76-89.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Community and home **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 36% of sample had CES-D scores=>16 **N (number randomised):** 278 **Mean age (years):** Not reported **Risk factor/s:** Psychosocial risk factors **Inclusion criteria:** i) Pregnant Latina woman; ii) aged at least 18 years old; iii) resident of Southwest Detroit; iv) <20 weeks gestational at the eligibility screening **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Healthy MOMs Lifestyle Intervention **Description:** The Healthy MOMs Lifestyle intervention consisted of group meetings and home visits during the antenatal and postnatal period and provided information, and encouraged discussion and activites aimed at reducing social and environmental barriers to healthy eating and regular exercise. Social support from the group leaders and peers was a key component of the intervention. Home visits were similar in curricular content to group meetings but community health workers also encouraged women to develop and review behavioural goals and provided emotional support. Optional weekly healthy eating and exercise group activities, such as healthy food/cooking demonstrations, walking groups, or aerobic dancing, were also offered and participants attended an average of five activity days. **Format:** Group and Individual **Group size:** Not reported **Sessions:** 11 **Frequency (number of doses per week):** 0.6 **Duration (weeks):** 17 **Provider:** Community health workers **Control intervention** **Name:** Enhanced Treatment as usual **Description:** The control group intervention included non-mental health focused education and support groups with some overlapping content with the intervention group (educational content regarding pregnancy, childbirth and the postpartum period, and identifying and managing stress and identifying signs and symptoms of depression) but without the focus on healthy eating and exercise (apart from standard pregnancy educational materials about eating and exercise). Participants in both groups also received ''The Little Pregnancy Book'', which reviewed maternal and fetal/newborn development and care; and monthly newsletters with health tips.

	Format: Group **Group size:** Not reported **Sessions:** 2 **Frequency (number of doses per week):** 0.2 **Duration (weeks):** 17 **Provider:** Community health workers
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (CES-D) **Outcomes not used:** Data cannot be extracted for depression symptomatology (CES-D>16) as sample size in each group is not reported so not possible to compute events from percentage. Data not extracted for 'immediately after the intervention during pregnancy (follow-up)' time point as this is actually mid-treatment as the intervention continues in the postnatal period
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health (R18 DK062433); the Biostatistics and Measurement Cores of the Michigan Diabetes Research and Training Center (National Institute of Diabetes and Digestive and Kidney Diseases, P60 DK020572; The Centers for Disease Control and Prevention, Division of Nutrition and Physical Activity (U48/CCUS1577S-/SIP 10) the Maternal and Child Health Bureau, Health Resources and Services Administration (R40 MC00115-03) and the University of Michigan Vivian A. and James L. Curtis School of Social Work Research and Training Center
Limitations	1. Risk of selection bias is unclear/unknown due to statistically significant group difference at baseline with a larger proportion of women in the intervention group who did not speak any English 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data cannot be extracted for depression symptomatology (CES-D>16) as sample size in each group is not reported so not possible to compute events from percentage
Notes	None

1.5.12 MEIJSSEN2010A/2010B/2011

Study ID	MEIJSSEN2010A/2010B/2011
Bibliographic reference	Meijssen D, Wolf M-J, Koldewijn K, Houtzager BA, van Wassenaer A, Tronick E, et al. The effect of the infant behavioral assessment and intervention program on mother-infant interaction after very preterm birth. Journal of Child Psychology and Psychiatry. 2010a;51:1287-1295. Meijssen DE, Wolf MJ, Koldewijn K, van Wassenaer AG, Kok JH, van Baar AL. Parenting stress in mothers after very preterm birth and the effect of the infant behavioural assessment and intervention program. Child: Care, Health and Development. 2010b;37:195-202. Meijssen D, Wolf M-J, Koldewijn K, van Baar A, Kok J. Maternal psychological distress in the first two years after very preterm birth and early intervention. Early Child Development and Care. 2011;181:1-11.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the

	participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Home **Country:** Netherlands
Participants	**Timing:** Postnatal **Baseline symptoms:** Without diagnosis **N (number randomised):** 176 **Mean age (years):** 32.2 **Risk factor/s:** Preterm or low birthweight baby (mean gestational age=29.8 weeks and mean birth weight=1286g) **Inclusion criteria:** i) All infants with a gestational age of <32 weeks and/or a birthweight of <1500 grams, admitted to one of these seven hospitals who survived to a post-menstrual age of 32-34 weeks; ii) parents were living in Amsterdam **Exclusion criteria:** i) Infants with severe congenital abnormalities; ii) mothers who had a documented history of illicit drug use or severe physical or mental illness; iii) non-Dutch speaking families for whom an interpreter could not be arranged; iv) infants who participated in other trials on post discharge management
Interventions	**Experimental intervention** **Name:** Infant Behavioural Assessment and Intervention Program (IBAIP) **Description:** Infant Behavioural Assessment and Intervention Program (IBAIP) was a post-discharge preventive intervention programmeaimed at enhancing the infant's social and environmental interactions. The intervention is guided by the Infant Behavioural Assessment (IBA), which helps the interventionist make parents aware of their baby's response to information. After each intervention session, parents received a report, which described the infant's neurobehavioural and developmental progress and gave suggestions on how to support the infant's explorations and self-regulatory competence, like support of posture and a graded input of information. **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Paediatric physical therapists **Control intervention** **Name:** Treatment as usual **Description:** Regular visits to the paediatrician in the local outpatient paediatric clinic. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Paediatrician
Outcomes	**Outcomes used:** Drop-out; Mother-infant interactions (ICEP and MSRS); Parental stress (NOSIK/NOSI); General mental health (GHQ-28) **Outcomes not used:** Data not extracted for the Still-face or Reunion behavioural observations or for environment-focused, stress, oral S-C, self-clasp, non-infant focused, social monitor/nvc, or social monitor/pvc subscales

	of the ICEP or undercontrol/withdrawn subscale of the MSRS. Data not use for 12-month measure of GHQ-28 as overlap for long follow-up category and so longest follow-up (24 months PP) prioritised
Study design	Randomised controlled trial (RCT)
Source of funding	Grants from the Innovatiefonds Zorgverzekeraars, project number 576 and ZonMw (Zorg Onderzoek Nederland): project number 62200032.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with analysis method as available case reported and not possible to compute ITT (WCS) 3. Risk of selective reporting bias is unclear/unknown
Notes	Paper reports that protocol registered (ISRCTN65502576) but cannot be found. Data requested from authors, and reply pending for: Standard deviations for all means (including GHQ raw data)

1.5.13 MELNYK2006

Study ID	MELNYK2006
Bibliographic reference	Melnyk BM, Feinstein NF, Alpert-Gillis L, Fairbanks E, Crean HF, Sinkin RA, et al. Reducing premature infants' length of stay and improving parents' mental health outcomes with the Creating Opportunities for Parent Empowerment (COPE) neonatal intensive care unit program: a randomized, controlled trial. Pediatrics. 2006;118:e1414-e1427.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 260 **Mean age (years):** 27.8 **Risk factor/s:** Preterm or low birthweight baby (mean gestational age was 31 weeks and mean birth weight was 1650g) **Inclusion criteria:** i) Women aged at least 18 years old; ii) who could read and speak English; iii) who had infants at gestational age of 26 to 34 weeks inclusive; iv) infants with a birth weight of 2500 g and appropriate for gestational age; v) infants expected to survive; vi) singleton birth **Exclusion criteria:** i) Women who had had another infant admitted to the NICU; ii) infants with severe handicapping conditions including grade III or IV intraventricular hemorrhage; iii) infants born at other sites; iv) infants with severe congenital abnormalities; v) mothers had a documented history of illicit drug use or severe physical or mental illness; vi) non-Dutch speaking families for whom an interpreter could not be arranged; vii) infants who participated in other trials on post discharge management
Interventions	**Experimental intervention** **Name:** Educational-behavioral intervention program (Creating Opportunities for Parent Empowerment)

	Description: A 4-phase educational-behavioral intervention program delivered using written and audiotaped formats. Each phase provides parents with information on (1) the appearance and behavioral characteristics of premature infants (infant-behavior information) and how parents can participate in their infants'care, meet their infants' needs, enhance quality of interaction with their infant, and facilitate their infant's development (parent-role information) and (2) activities that assist parents in implementing the experimental information. **Format:** Individual **Group size:** N/A **Sessions:** 4 (intervention delivered in written and audiotaped format) **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Research nurse **Control intervention** **Name:** Enhanced Treatment as usual **Description:** A 4-phase series of audiotapes and written information. The first 2 tapes provided information about hospital services, the third tape contained discharge information given to all parents, and the fourth tape had information regarding immunizations. **Format:** Individual **Group size:** N/A **Sessions:** 4 intervention sessions delivered at the same times as the 4 phases of the COPE program **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Research nurse
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (BDI-II); Anxiety mean scores (STAI); Parental stress (PSS-NICU); Mother-infant interaction (IPBN); Maternal confidence (PBS-NICU); Infant service use (LOS) **Outcomes not used:** Data could not be extracted for infant length of hospital stay (primary outcome) as Ns not reported. Data was not extracted for other time points (time 1-4 & 6) where post-intervention (time 5) data were available
Study design	Randomised controlled trial (RCT)
Source of funding	National Institutes of Health/National Institute of Nursing Research grant R01 05077
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with analysis method as paper reports available case and not possible to compute ITT (WCS) 4. High risk of selective reporting bias as data could not be extracted for infant length of hospital stay (primary outcome) as Ns not reported
Notes	None

1.5.14 MEYER1994

Study ID	MEYER1994
Bibliographic reference	Meyer EC, Coll CTG, Lester BM, Boukydis CFZ, McDonough SM, et al.

	Family-based intervention improves maternal psychological well-being and feeding interaction of preterm infants. Pediatrics. 1994;93:241-246.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** 35% BDI=>9 **N (number randomised):** 34 **Mean age (years):** 27.9 **Risk factor/s:** Preterm delivery **Inclusion criteria:** i) Preterm infants hospitalized in the Special Care Nursery at Women and Infants' Hospital of Rhode Island; ii) birth weight < l500 g **Exclusion criteria:** i) Congenital anomalies; ii) intrauterine growth retardation; iii) child protection service involvement; iv) substance abuse; v) serious psychiatric conditions
Interventions	**Experimental intervention** **Name:** Individualised Family-Based Intervention **Description:** Case management and individualized treatment. The treatment for families in the intervention was designed based on an interdisciplinary conference in which parents' responses to the standardised assessment battery were reviewed. Parents were also interviewed using the Clinical Interview For Parents of High-Risk Infants that addressed several areas including: infant's current condition, pregnancy, labour and delivery, relationship with infant and feelings as a parent, reaction to the intensive care nursery and relationship with staff, family and social support, and discharge. Intervention strategies were customized according to the infant's and family's needs. Siblings and extended family members were included as determined by parental preference and individualized planning with the care manager. The intervention addressed four major domains including: infant behaviour and characteristics; family organisation and functioning; caregiving environment; and home discharge and community resources. The duration of intervention (range 2 to 8 weeks) and number of intervention sessions (range 3 to 17) were determined based on length of hospitalization and intervention needs, in keeping with the individualized nature of the program. Intervention sessions generally lasted 1 to 1.5 hours depending on the particular interventions that were provided. **Format:** Individual **Group size:** N/A **Sessions:** 10 (median) **Frequency (number of doses per week):** 2 (median) **Duration (weeks):** 5 (median) **Provider:** Coordinated by one clinician (care manager) from an interdisciplinary team which included pediatrics, psychology, nursing, and physical therapy **Control intervention** **Name:** Treatment as usual **Description:** Standard nursery care included medical and nursing treatment of the infant, and assignment of a social worker. **Format:** Individual **Group size:** N/A

	Sessions: Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 5 (median) **Provider:** Nurses and Social worker
Outcomes	**Outcomes used:** Depression symptomatology (BDI=>9); Parental stress (PSS: NICU); self-esteem (MSRI); Maternal sensitivity (behavioural observation of feeding interaction) **Outcomes not used:** Data not extracted for negative infant behaviour, negative maternal behaviour, positive maternal behaviour, quality of physical contact or positive affect
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Mental Health (NIMH 1T24 MH18809)
Limitations	1. High risk of selection bias as randomisation method and allocation concealment are unclear and there was a statistically significant baseline difference in maternal age (29.7 in intervention group and 25.9 in control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.5.15 NEWNHAM2009

Study ID	NEWNHAM2009
Bibliographic reference	Newnham CA, Milgrom J, Skouteris H. Effectiveness of a modified mother-infant transaction program on outcomes for preterm infants from 3 to 24 months of age. Infant Behavior and Development. 2009;32:17-26.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital (and 1 session at home) **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Mean EPDS = 7.29 (SD = 4.69) **N (number randomised):** 68 **Mean age (years):** 31.5 **Risk factor/s:** Preterm or low birthweight baby (mean gestational age=32.4 weeks and mean birthweight=1604g) **Inclusion criteria:** i) Mothers with an infant with a gestational age of <37 weeks **Exclusion criteria:** i) Infants with congenital abnormalities; ii) infants with gross neurological damage; iii) infants who were triplets or higher multiples; iv) parents who were non-English speaking; v) parents who were drug dependent
Interventions	**Experimental intervention** **Name:** Modified Mother–Infant Transaction Program **Description:** The content of the intervention was largely based on the Mother-Infant Transaction Program (MITP;Rauh et al., 1990) except for the inclusion of

	information about kangaroo care, massage and an infant bath session which was used as an educational aid. Learning methods included verbal instruction, infant observation, practical experience in handling infants nd modelling, as well as written materials.Session 1: Becoming acquainted; Sessions 2–7: Recognising infant disorganisation/stress and availability and then applying those principles during care and play; Session 8: Home visit (1 month); Session 9: Follow-up hospital visit (3 months). **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** Variable **Duration (weeks):** 15 **Provider:** Researcher **Control intervention** **Name:** Treatment as usual **Description:** Following the initial interview which was the same as for the intervention mothers, control infants and mothers received standard hospital care. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Mean depression scores (EPDS); Mother-infant attachment (Synchrony Scale); Infant emotional development (STSI-Approach [social withdrawal]); Infant physical development (colic, sleep, behavioural problems [crying]); parental stress (PSI) **Outcomes not used:** Data cannot be extracted for all subscales due to selective reporting, and data cannot be extracted for the Ages and Stages Questionnaire (ASQ)
Study design	Randomised controlled trial (RCT)
Source of funding	Medical Research Foundation for Women and Babies
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data cannot be extracted for all subscales or for the Ages and Stages Questionnaire (ASQ)
Notes	Data requested, and author response pending for: Means and standard deviations of all scores on all (subscales) of measures taken. Details of allocation concealment for randomisation

1.5.16 PHIPPS2013

Study ID	PHIPPS2013
Bibliographic reference	Phipps MG, Raker CA, Ware CF, Zlotnick C. Randomized controlled trial to prevent postpartum depression in adolescent mothers. American Journal of Obstetrics and Gynecology. 2013;208: 192.e1-6.

Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** History of depression, n (%): 17 (16%) **N (number randomised):** 106 **Mean age (years):** Not reported (Median: 16) **Risk factor/s:** Adolescence and Psychosocial risk factors **Inclusion criteria:** i) = <17 years old when they conceived their pregnancy; ii) <25 weeks gestational age at their first prenatal visit **Exclusion criteria:** i) received mental health services from a healthcare provider; ii) met criteria for a current affective disorder, substance use disorder, anxiety disorder (excluding simple phobia), or psychosis (as assessed by the KID-SCID)
Interventions	**Experimental intervention** **Name:** REACH program intervention + Baby Basics book **Description:** An adaptation of an interpersonal therapy–based prevention which includes multimedia (video snippets), interactive (role-playing) components, and homework with feedback. The content of the REACH program focused on the development of effective communication skills to manage relationship conflicts before and after the birth of the baby, expectations about motherhood, stress management, "baby blues" vs depression, development of a support system, development of healthy relationships, goal setting, and psychosocial resources for new mothers **Format:** Group and Individual **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 5 **Provider:** Not reported **Control intervention** **Name:** Enhanced Treatment as usual **Description:** The attention and dose-matched control condition involved using the Baby Basics book as a guide for the didactic control program. This program included information about maternal health throughout pregnancy and the early postpartum period, fetal development, nutrition, preparation for labor, and preparation of the home for taking a baby home **Format:** Group and Individual **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 5 **Provider:** Not reported
Outcomes	**Outcomes used:** Diagnosis of major depressive disorder (Structured Clinical Interview for the Diagnostic and Statistical Manual for Mental Disorders, 4th edition, [DSM-IV] Childhood Diagnoses [KID-SCID]) **Outcomes not used:** Not reported
Study design	Randomised controlled trial (RCT)

Source of funding	Grant from the National Institute of Mental Health (R34MH77588)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as outcome data only reported at 6-months and no data for 6 weeks and 3-months after delivery
Notes	None

1.5.17RAVN2012

Study ID	RAVN2012
Bibliographic reference	Ravn IH, Smith L, Smeby NA, Kynoe NM, Sandvik L, Bunch EH, et al. Effects of early mother-infant intervention on outcomes in mothers and moderately and late preterm infants at age 1 year: a randomized controlled trial. Infant Behavior and Development. 2012;35:36-47.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital and home **Country:** Norway
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 106 **Mean age (years):** 30.9 **Risk factor/s:** Preterm delivery (mean gestational age=33.2 weeks, mean birthweight=1917g) **Inclusion criteria:** i) Parents of preterm infants with ultrasound gestational age of 30-36 weeks; ii) parents who could speak, read and write Norwegian; iii) had no history of drug/alcohol abuse or severe psychiatric disorders; iv) if hospital stays of at least eight days were anticipated **Exclusion criteria:** i) Infants with congenital anomalies, neurological sequelae, hearing loss or chromosomal disorders
Interventions	**Experimental intervention** **Name:** Mother-Infant Transaction Program (MITP) **Description:** The Mother-Infant Transaction Program (MITP) was aimed at helping parents to appreciate their infant's unique characteristics, temperament and developmental potential, and to assist the parents in being more sensitive and responsive to their infants' physiological and social cues, particularly those that signal stimulus overload, and to establish a good pattern of interaction **Format:** Individual **Group size:** N/A **Sessions:** 11 **Frequency (number of doses per week):** Variable (eleven-session one-hour sessions were carried out 7-10 days before discharge, four were given at home during the first three months) **Duration (weeks):** 14 **Provider:** Trained neonatal nurses **Control intervention** **Name:** Treatment as usual

	Description: All groups received the unit's standardized protocol before discharge **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 14 **Provider:** Not reported
Outcomes	**Outcomes used:** Drop out; Depression symptomatology (CES-D>16); Mother-infant attachment (discontinued breastfeeding); Parental stress (PSI); Infant social-communication development (PICS) **Outcomes not used:** Data not extracted for Infant Behavior Questionnaire (IBQ) or for subscales of the PICS. Data not extracted for 1-month time point as mid-treatment
Study design	Randomised controlled trial (RCT)
Source of funding	The South-Eastern Norway Regional Health Authority; The Royal Norwegian Ministry of Health; The Centre for Child and Adolescent Mental Health, East and Southern Norway; Woman & Children's Division Oslo University hospital, Ullevaal, The Department of Nursing research in Oslo University Hospital, Ullevaal, and Norwegian Nurses Association
Limitations	1. High risk of selection bias as statistically significant baseline difference with the intervention group having more mothers with earlier preterm birth and non-Norwegian origin 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with method of analysis as paper reports available case and although where possible ITT (WCS) was computed this could not be computed for all outcome measures 4. High risk of selective reporting bias as data not reported for parents' sensitivity/responsitivity to children's behaviour/signals
Notes	None

1.5.18 SEN2006/DENNIS2013

Study ID	SEN2006/DENNIS2013
Bibliographic reference	Sen DM. A randomized controlled trial of midwife-led twin antenatal program – The Newcastle twin study [thesis]. Newcastle-upon-Tyne: University of Newcastle; 2006. Dennis CL, Dowswell T. Psychosocial and psychological interventions for preventing postpartum depression. Cochrane Database of Systematic Reviews. 2013;2: CD001134.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital, community and home **Country:** UK
Participants	**Timing:** Antenatal and postnatal

	Baseline symptoms: Not reported **N (number randomised):** 162 **Mean age (years):** Not reported **Risk factor/s:** Multiple pregnancy (uncomplicated twin pregnancy) **Inclusion criteria:** i) Women with uncomplicated twin pregnancy at < 20 weeks' gestation **Exclusion criteria:** i) Women having fetal or infant death
Interventions	**Experimental intervention** **Name:** Home visits, psychoeducation (non-mental health-focused) and care in hospital **Description:** At least 2 home visits (1 antenatal and 1 in the early postpartum); specially designed antenatal preparation for parenting program (4-5 antenatal group classes and 1 postnatal class); care in-hospital and at out-patient hospital clinic) **Format:** Individual and Group **Group size:** Not reported **Sessions:** 8 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Trained midwife/prenatal care provider **Control intervention** **Name:** Treatment as usual **Description:** Shared antenatal care between GP and consultant obstetrician at a twin clinic; allocation to a community midwife who may provide care in conjunction with GP; invitation to attend community-based antenatal education sessions (normally without a focus on twins); invitation to a breastfeeding workshop (rarely with focus on twins); self-referral to Childbirth Trust antenatal sessions (without focus on twins) **Format:** Individual and Group **Group size:** Not reported **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** GP, consultant obstetrician, and community midwife.
Outcomes	**Outcomes used:** Depression symptomatology (measure and threshold not reported but assumption made that EPDS>12); Mean depression score (EPDS), mean anxiety score (HADS), mean parenting stress (PSI); mother/infant interaction (Green scale); Social support (Satisfaction with Motherhood subscale); General outlook on life, emotional wellbeing and satisfaction with care **Outcomes not used:** Marital relationship (VAS developed by researcher)
Study design	Randomised controlled trial (RCT)
Source of funding	None acknowledged
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with method of analysis as DENNIS2013 reports available case and although where possible ITT (WCS) was computed this could not be computed for all outcome measures 3. High risk of selective reporting bias as data cannot be extracted from DENNIS2013 for 52 week follow-up for maternal-infant attachment, anxiety or perceived social support; or for post-treatment, 12-week or

	52-week follow-up for parental stress 4. Risk of attrition bias was unclear/unknown
Notes	Could not access the unpublished data, data extracted from DENNIS2013

1.5.19 SMALL2000 /2006

Study ID	SMALL2000 /2006
Bibliographic reference	Small R, Lumley J, Donohue L, Potter A, Waldenström U. Randomised controlled trial of midwife led debriefing to reduce maternal depression after operative childbirth. BMJ. 2000;321:1043-1047. Small R, Lumley J, Toomey L. Midwife-led debriefing after operative birth: four to six year follow-up of a randomised trial. BMC Medicine. 2006;4:3.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 1041 **Mean age (years):** Not reported **Risk factor/s:** Operative delivery (26% elective caesarean; 33% emergency caesarean; 35% forceps; 6% vacuum extraction) **Inclusion criteria:** i) women who had given birth by caesarean section or with the use of forceps or vacuum extraction **Exclusion criteria:** i) poor infant or maternal health post-delivery; ii)women who had had stillbirths or babies weighing less than 1500 g; iii) women with insufficient English to take part; iv) women whose private obstetricians had refused permission to approach them
Interventions	**Experimental intervention** **Name:** Midwife-led postnatal debriefing + pamphlet **Description:** The debriefing intervention provided women with an opportunity to discuss their labour, birth, and post-delivery events and experiences. Debriefing took place before the women were discharged from hospital. Midwives were experienced in talking with women about birth, able to listen with empathy to women's accounts, and aware of the common concerns and issues arising for women after an operative birth. Content of the discussion was determined by each woman's experiences and concerns, and up to one hour was made available for the session. Women allocated to debriefing also received a pamphlet on sources of assistance for mothers. **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session **Provider:** Midwife **Control intervention** **Name:** Treatment as usual

	Description: Women allocated to standard care received a brief visit from the midwife to give them a pamphlet on sources of assistance for mothers on discharge from hospital. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS>13); Depresison mean scores (EPDS); General mental health mean scores (SF-36 MCS) **Outcomes not used:** Data not extracted for all subscales (except MCS) of the SF-36 or for maternal report of depression as a problem as EPDS data used
Study design	Randomised controlled trial (RCT)
Source of funding	Research and development grants advisory committee of the Australian Commonwealth Department of Health, Housing, and Community Services
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with method of analysis is unclear as paper reports available case and although where possible ITT (WCS) was computed this could not be computed for all outcome measures 3. Risk of selective reporting bias was unclear/unknown
Notes	None

1.5.20 SPITTLE2010/2009/SPENCERSMITH2012

Study ID	SPITTLE2010/2009/SPENCERSMITH2012
Bibliographic reference	Spittle AJ, Anderson PJ, Lee KJ, Ferretti C, Eeles A, Orton J, et al. Preventative care at home for very preterm infants improves infant and caregiver outcomes at 2 years. Pediatrics. 2010;126:e171-e178. Spittle AJ, Ferretti C, Anderson PJ, Orton J, Eeles A, Bates L, et al. Improving the outcome of infants born at <30 weeks' gestation – a randomized controlled trial of preventative care at home. BMC Pediatrics. 2009;9:73. Spencer-Smith MM, Spittle AJ, Doyle LW, Lee KJ, Lorefice L, Suetin A, et al. Long-term benefits of home-based preventive care for preterm infants: a randomized trial. Pediatrics. 2012;130: 1094-1101.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Depression (EPDS score of = > 13): 12.5% **N (number randomised):** 120 **Mean age (years):** Not reported

	Risk factor/s: Preterm delivery **Inclusion criteria:** i) infants born at <30 weeks' gestational age with no major congenital anomalies associated with a poor neurodevelopmental outcomes **Exclusion criteria:** i) if the family did not live within a 100-km radius of the hospital; ii) if the family spoke no English; iii) if infants were still in hospital at 4 weeks' corrected age
Interventions	**Experimental intervention** **Name:** VIBeS Plus Intervention **Description:** VIBeS Plus Intervention designed by a multidisciplinary team. The actual intervention involved 2 components: i) Physiotherapy to improve functional use of movement and limit disability in the infant, this included improving infant's postural control, behavioural regulation and mobility through education of parents on positioning, carrying and play ideas. ii) A psychological component to support families by a) supporting maternal mental health in the adjustment to mothering a preterm infant and discussing challenges in bringing the infant home b) providing an outlet for debriefing about the experience of preterm delivery and supporting the mother to deal with emotional reactions to preterm birth c) providing a brief therapeutic intervention and referral for further support for symptoms of anxiety or depression d) supporting parents with social support networks. **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** 0.17 **Duration (weeks):** 52 **Provider:** Physiotherapist and psychologist **Control intervention** **Name:** Treatment as usual **Description:** Standard non-systematic follow-up care; each family had access to a maternal and child health nurse in the community, who assessed the developmental progress of the child among other well-child health tasks, such as weighing and immunizations **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 52 **Provider:** Maternal and child health nurse
Outcomes	**Outcomes used:** Depression mean score (HADS) and symptomatology (HADS>7/8); Anxiety mean score (HADS) and symptomatology (HADS>7/8); Physical development of infant (Movement Assessment Battery for Children-mean score and symptomatology [scores=<15th percentile]); Cognitive development of infant (Bayley Scales of Infant and Toddler Development III-mean scores and symptomatology [scores<70]; Differential Ability Scale-mean score and symptomatology [scores>1 SD below test mean]); Emotional development of infant (Infant-Toddler Social and Emotional Assessment-mean scores and symptomatology [scores=>90th percentile/=<10th percentile]; Behavioral Assessment Screener for Children-mean scores and symptomatology [scores >1 SD above/below test mean]); Drop-out **Outcomes not used:** No endoint/post-treatment data available for outcome at 1-year. Data not reported for: Parental stress (PSI); Family burden (IOF-G and FAD); Social support (SSQ); Child-parent interaction (behavioural

	observation)
Study design	Randomised controlled trial (RCT)
Source of funding	National Health and Medical Council
Limitations	1. High risk of selection bias due to baseline differences between groups with twice the number of participants showing depression symptomatology (EPDS=>13) in the control group (N=10/17%) relative to the intervention group (N=5/8%) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with method of analysis is unclear as paper reports available case and although where possible ITT (WCS) was computed this could not be computed for all outcome measures 4. High risk of selective reporting bias as no post-treatment/endpoint data reported for outcomes at 1-year. Data was also not reported for: Parental stress (PSI); Family burden (IOF-G and FAD); Social support (SSQ); Child-parent interaction (behavioural observation)
Notes	Protocol registered: ACTRN12605000492651

1.5.21 STAMP1995

Study ID	STAMP1995
Bibliographic reference	Stamp GE, Williams AS, Crowther CA. Evaluation of antenatal and postnatal support to overcome postnatal depression: a randomized, controlled trial. Birth. 1995;22:138-143.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (primary) **Country:** Australia
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Not reported **N (number randomised):** 144 **Mean age (years):** 26.5 **Risk factor/s:** Uncertain ('at risk') **Inclusion criteria:** i) English-speaking women; i) a singleton pregnancy of less than 24 weeks' gestation; iii) lived within the metropolitan area and agreed to attend extra groups if invited; iv) scored 2 or more on the modified screening questionnaire (for risk factors) **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Preventative intervention **Description:** The groups included a practical and emotional emphasis on planning for and expectations of life changes precipitated by the arrival of a new baby. Its focus was on access to information, preparation and support, the extension and development of women's existing networks, and goal setting. Women were given simple suggestions to reduce stress after the birth of the baby, including to ignore unwanted advice, obtain support from one or two trusted people, form a relationship with supportive professionals, and keep

	the list of resources and goals in an obvious place. The postnatal group was intended as a time for women to share their birth stories, talk about the impact of a new baby on their lives, and discuss what resources had or had not worked. **Format:** Group **Group size:** 10 **Sessions:** 3 **Frequency (number of doses per week):** 0.25 **Duration (weeks):** 13 **Provider:** Midwife **Control intervention** **Name:** Treatment as usual **Description:** Antenatal classes offered by the hospital including infomation about postnatal depression at 6-weeks postntally **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 13 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS>12) **Outcomes not used:** Data was not extracted for minor depression (EPDS>9) as major depression cut-off (EPDS>12) more widely used as a measure of depression symptomatology across studies; Data was not used in the meta-analysis for short-term follow-up as this was a 6-week post-treatment follow-up and therefore falls outside of the short-term follow-up range (9-16 weeks)
Study design	Randomised controlled trial (RCT)
Source of funding	Grants from the Queen Victoria Hospital Foundation, Section 16 of the South Australian Health Commission, Centre for Nursing Research, and the Australian College of Midwives Inc.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.5.22WEBSTER2003

Study ID	WEBSTER2003
Bibliographic reference	Webster J, Linnane J, Roberts J, Starrenburg S, Hinson J, Dibley L. IDentify, Educate and Alert (IDEA) trial: an intervention to reduce postnatal depression. BJOG. 2003;110:842-846.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Australia
Participants	**Timing:** Antenatal **Baseline symptoms:** Only intervention group were screened: 27.5% EPDS>12

	N (number randomised): 600 **Mean age (years):** 27.2 **Risk factor/s:** Psychosocial risk factors (low social/partner support) or (family) history of mental health problems (own or family member's previous history of mental illness, particularly postnatal depression) **Inclusion criteria:** i) the presence of any of the following risk factors for postnatal depression: (1) low social or partner support, measured by a score of 24 or less on the Maternity Social Support Scale, (2) a past history of mental illness, (3) family psychiatric history, (4) past postnatal depression or (5) having a mother who had postnatal depression **Exclusion criteria:** i) no risk factors; ii) insufficient literacy/English; iii) >36 weeks' gestation at booking
Interventions	**Experimental intervention** **Name:** Psychoeducation booklet **Description:** The intervention consisted of an information booklet about postnatal depression, which included contact numbers for postnatal depression resources. The intervention group also completed prenatal screening using the Edinburgh Postnatal Depression Scale and were able to discuss their risk of developing postnatal depression. Finally, the 'alert' component of the intervention involved a letter being sent to the woman's referring GP and local Child Health Nurse, alerting them of the woman's risk for postnatal depression. **Format:** Not reported **Group size:** Not reported **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** As required **Control intervention** **Name:** Treatment as usual **Description:** Case management and referral to hospital social worker/ psychiatrist as required **Format:** Not reported **Group size:** Not reported **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** As required
Outcomes	**Outcomes used:** Depression symptomatology (EPDS >12) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of selection bias with a statistically significant group difference at baseline (control group younger than intervention group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.6 PSYCHOSOCIAL INTERVENTIONS: PREVENTION (RISK FACTORS IDENTIFIED) – EXCLUDED STUDIES

Study	Reason for exclusion
Barlow A, Mullany B, Neault N, Compton S, Carter A, Hastings R, et al. Effect of a paraprofessional home-visiting intervention on American Indian teen mothers' and infants' behavioral risks: a randomized controlled trial. American Journal of Psychiatry. 2013;170:83-93.	Data cannot be extracted (no means or SDs provided for outcomes)
Barnes J, Senior R, MacPherson K. The utility of volunteer home-visiting support to prevent maternal depression in the first year of life. Child: care, health and development . 2009;35:807-816.	Group allocation was not randomised
Beeber LS, Holditch-Davis D, Perreira K, Schwartz TA, Lewis V, Blanchard H, et al. Short-term in-home intervention reduces depressive symptoms in Early Head Start Latina mothers of infants and toddlers. Research in Nursing and Health. 2010;33:60-76.	Age of infant over one year
Beeber LS, Schwartz TA, Holditch-Davis D, Canuso R, Lewis V, Hall HW. Parenting enhancement, interpersonal psychotherapy to reduce depression in low-income mothers of infants and toddlers. Nursing Reseach. 2013;62:82-90.	Age of infant over one year
Cho Y, Hirose T, Tomita N, Shirakawa S, Murase K, Komoto K. Infant mental health intervention for preterm infants in Japan: promotions of maternal mental health, mother-infant interactions, and social support by providiing continuous home visits until the corrected infant age of 12 months. Infant Mental Health Journal. 2013;34:47-59.	Group allocation was not randomised
Chourasia N, Surianarayanan P, Bethou A, Bhat V. Stressors of NICU mothers and the effect of counseling—experience from a tertiary care teaching hospital, India. Journal of Maternal-Fetal and Neonatal Medicine. 2013; 26:616–618.	No mental health outcome reported
Ciftci EK, Arikan D. The effect of training administered to working mothers on maternal anxiety levels and breastfeeding habits. Journal of Clinical Nursing. 2012;21:2170-2178.	Group allocation was not randomised
Crockett K, Zlotnick C, Davis M, Payne N, Washington R. A depression preventive intervention for rural low-income African-American pregnant women at risk for postpartum depression. Archives of Women's Mental Health. 2008;11:319-325.	Data cannot be extracted
Cupples ME, Stewart MC, Percy A, Hepper P, Murphy C, Halliday HL. A RCT of peer-mentoring for first-time mothers in socially disadvantaged areas (the MOMENTS study). Archives of Disease in Childhood. 2011;96:252-258.	No mental health outcome reported
Curry MA, Durham L, Bullock L, Bloom T, Davis J. Nurse case management for pregnant women experiencing or at risk for abuse. Journal of Obstetric, Gynecologic, and Neonatal Nursing. 2006;35:181-192.	No mental health outcome reported
Eckenrode J, Campa M, Luckey DW, Henderson CR Jr, Cole R, Kitzman H, et al. Long-term effects of prenatal and infancy nurse home visitation on the life course of youths: 19-year follow-up of a randomized trial. Archives of Pediatrics and Adolescent Medicine. 2010;164:9-15. Kitzman HJ, Olds DL, Cole RE, Hanks CA, Anson EA, Arcoleo KJ, et al. Enduring effects of prenatal and infancy home visiting by nurses on children: follow-up of a randomized trial among children at age 12 years. Archives of Pediatrics and Adolescent Medicine. 2010;164:412-418.	No mental health outcome reported (and paper unavailable for Kitzman et al., 1997)

Kitzman H, Olds DL, Henderson CR Jr, Hanks C, Cole R, Tatelbaum R, et al. Effect of prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood injuries, and repeated childbearing: a randomized controlled trial. JAMA. 1997;278:644-652. Kitzman H, Olds DL, Sidora K, Henderson CR Jr, Hanks C, Cole R, et al. Enduring effects of nurse home visitation on maternal life course: a 3-year follow-up of a randomized trial. JAMA. 2000;283:1983-1989. Olds DL, Kitzman HJ, Cole RE, Hanks CA, Arcoleo KJ, Anson EA, et al. Enduring effects of prenatal and infancy home visiting by nurses on maternal life course and government spending: follow-up of a randomized trial among children at age 12 years. Archives of Pediatrics and Adolescent Medicine. 2010;164:419-424. Olds DL, Kitzman H, Cole R, Robinson J, Sidora K, Luckey DW, et al. Effects of nurse home-visiting on maternal life course and child development: age 6 follow-up results of a randomized trial. Pediatrics. 2004;114:1550-1559. Olds DL, Kitzman H, Hanks C, Cole R, Anson E, Sidora-Arcoleo K, et al. Effects of nurse home visiting on maternal and child functioning: age-9 follow-up of a randomized trial. Pediatrics. 2007; 120:e832-e845.	
Franck LS, Oulton K, Nderitu S, Lim M, Fang S, Kaiser A. Parent involvement in pain management for NICU infants: a randomized controlled trial. Pediatrics. 2011;128:510-518.	No mental health outcome reported
Ginsburg GS, Barlow A, Goklish N, Hastings R, Varipatis Baker E, Mullany B, et al. Postpartum depression prevention for reservation-based American Indians: results from a pilot randomized controlled trial. Child and Youth Care Forum. 2012;41:229-245.	Not culturally relevant
Glazebrook C, Marlow N, Israel C, Croudace T, Johnson S, White IR, et al. Randomised trial of a parenting intervention during neonatal intensive care. Archives of Disease in Childhood Fetal and Neonatal Edition. 2007;92:F438-443.	Crossover study and not possible to extract disaggregated first phase data
Heinicke CM, Fineman NR, Ruth G, Recchia SL, Guthrie D. Relationship-based intervention with at-risk mothers: outcome in the first year of life. Infant Mental Health Journal. 1999;20:349-374.	Data cannot be extracted for mental health outcomes (emailed author for raw BDI and STAI continuous/dichotomous scores but no satisfactory response)
Ickovics JR, Reed E, Magriples U, Westdahl C, Rising SS, Kershaw TS. Effects of group prenatal care on psychosocial risk in pregnancy: results from a randomised controlled trial. Psychology and Health. 2011;26:235-250.	Data cannot be extracted from paper as no Ns are reported
Jallo N, Bourguignon C, Taylor AG, Ruiz J, Goehler L. The biobehavioral effects of relaxation guided imagery on maternal stress. Advances in Mind-body Medicine. 2009;24:12-22.	Paper unavailable
Joseph JG, El-Mohandes AA, Kiely M, El-Khorazaty MN, Gantz MG, Johnson AA, et al. Reducing psychosocial and behavioral pregnancy risk factors: results of a randomized clinical trial among high-risk pregnant african american women. American Journal of Public Health. 2009;99:1053-1061.	Data cannot be extracted

Kaaresen PI, Ronning JA, Ulvund SE, Dahl LB. A randomized, controlled trial of the effectiveness of an early-intervention program in reducing parenting stress after preterm birth. Pediatrics. 2006;118:e9-19.	No mental health outcome reported
Kershaw K, Jolly J, Bhabra K, Ford J. Randomised controlled trial of community debriefing following operative delivery. BJOG. 2005;112:1504–1509.	Data cannot be extracted (continuous data cannot be extracted as SDs not reported and dichotomous data not reported for endpoint)
Koh TH-H, Butow PN, Coory M, Budge D, Collie L-A, Whitehall J, et al. Provision of taped conversations with neonatologists to mothers of babies in intensive care: randomised controlled trial. British Medical Journal. 2007;334:28-31.	Intervention not relevant
Lai HL, Chen CJ, Peng TC, Chang FM, Hsieh ML, Huang HY, Chang SC. Randomized controlled trial of music during kangaroo care on maternal state anxiety and preterm infants' responses. International Journal of Nursing Studies. 2006;43:139-146.	Data cannot be extracted
Lara MA, Navarro C, Navarrete L. Outcome results of a psycho-educational intervention in pregnancy to prevent PPD: a randomized control trial. Journal of Affective Disorders. 2010a;122:109-117. Lara MA, Navarro C, Navarrete L, Le H-N. Retention rates and potential predictors in a longitudinal randomized control trial to prevent postpartum depression. Salud Mental. 2010b;33:429-436.	>50% dropout
LeCroy CW, Krysik J. Randomized trial of the healthy families Arizona home visiting program. Children and Youth Services Review. 2011;33:1761-1766.	No mental health diagnosis and no mental health outcomes
Marcenko MO, Spence M. Home visitation services for at-risk pregnant and postpartum women: a randomized trial. American Journal of Orthopsychiatry. 2004;64;468-478.	Paper unavailable
Marks MN, Siddle K, Warwick C. Can we prevent postnatal depression? A randomized controlled trial to assess the effect of continuity of midwifery care on rates of postnatal depression in high-risk women. Journal of Maternal-Fetal and Neonatal Medicine. 2003;13:119-127.	Outside scope (organisation of care)
Muthusamy AD, Leuthner S, Gaebler-Uhing C, Hoffmann RG, Li SH, Basir MA. Supplemental written information improves prenatal counseling: a randomized trial. Pediatrics. 2012;129:e1269-e1274.	Data cannot be extracted
Ryding EL, Wirén E, Johansson G, Ceder B, Dahlström AM. Group counseling for mothers after emergency cesarean section: a randomized controlled trial of intervention. Birth. 2004;31:247-253.	Group allocation was not randomised
Sáenz P, Cerdá M, Díaz JL, Yi P, Gorba M, Boronat N, et al. Psychological stress of parents of preterm infants enrolled in an early discharge programme from the neonatal intensive care unit: a prospective randomised trial. Archives of Disease in Childhood: Fetal and Neonatal Edition. 2009;94:F98-F104.	Outside scope (organisation of care)
Schwarz DF, O'Sullivan AL, Guinn J, Mautone JA, Carlson EC, Zhao H, et al. Promoting early intervention referral through a randomized controlled home-visiting program. Journal of Early Intervention. 2012;34:20-39.	Age of infant over one year
Sheeber LB, Seeley JR, Feil EG, Davis B, Sorensen E, Kosty DB, et al. Development and pilot evaluation of an internet-facilitated cognitive-behavioral intervention for maternal depression. Journal of Consulting and Clinical Psychology. 2012;80:739-749.	Age of infant over one year
Taft AJ, Small R, Hegarty KL, Watson LF, Gold L, Lumley JA. Mothers'	Sample not relevant

AdvocateS In the Community (MOSAIC)-non-professional mentor support to reduce intimate partner violence and depression in mothers: a cluster randomised trial in primary care. BMC Public Health. 2011;11:178.	
Turan T, Basbakkal Z, Ozbek S. Effect of nursing interventions on stressors of parents of premature infants in neonatal intensive care unit. Journal of Clinical Nursing. 2008;17:2856-2866.	No mental health outcome reported

1.7 PSYCHOSOCIAL INTERVENTIONS: PROTOCOLS FOR WOMEN FOLLOWING STILLBIRTH – INCLUDED STUDIES

1.7.1 CACCIATORE2008

Study ID	CACCIATORE2008
Bibliographic reference	Cacciatore J, Rådestad I, Frøen F. Effects of contact with stillborn babies on maternal 40 anxiety and depression. Birth. 2008;35:313-20.
Methods	**Recruitment and inclusion criteria:** Internet search engines and directories systematically searched to identify organizations offering information and support on pregnancy and childbirth (Including stillbirth). 37organizations accepted invitation to recruit women affected by stillbirth to respond to an online questionnaire. Women who had experienced a singleton stillbirth (>20 weeks gestation) were included **Country:** US (72%); UK (11%); Australia (9%); Canada (5%)
Participants	**Timing:** Not reported **N:** 2292 **Mean age (years):** Not reported **Pregnancy at time of participation:** 286 women (12%) pregnant at time of participation **Gestational age at loss:** Not reported (inclusion criteria: >20 weeks)
Study details	Data cannot be extracted. Narratively compare women who were or were not pregnant at time of completing questionnaire and women who did and did not hold their baby
Outcomes	Anxiety and depression symptomatology (HSCL-25>1.75)
Study design	Cohort (retrospective)
Source of funding	Norwegian Society for Unexpected Infant Death, Oslo, Norway
Limitations	Data cannot be extracted so study results cannot be meta-analysed
Notes	Data requested from author but no response

1.7.2 GRAVENSTEEN2013

Study ID	GRAVENSTEEN2013
Bibliographic reference	Gravensteen IK, Helgadóttir LB, Jacobsen E-M, Rådestad I, Sandset PM, et al. Women's experiences in relation to stillbirth and risk factors for long-term post-traumatic stress symptoms: a retrospective study. BMJ Open. 2013;3:e003323.
Methods	**Recruitment and inclusion criteria:** Hospital records used to identify verified diagnosis of stillbirth (=>23 gestational weeks or birth weight = >500g) in a singleton or twin pregnancy from 1 January 1990 to 31 December 2003 and a postal invitation sent to potential participants **Country:** Norway
Participants	**Timing:** 5-18 years after stillbirth (mean: 10.8 years) **N:** 379 identified; data only available for 101 who completed all questionnaires **Mean age (years):** At time of stillbirth: 30.8; At time of participation: 41.6

	Pregnancy at time of participation: None of the women were pregnant at follow-up; mean of 2.2 live-born children **Gestational age at loss:** Not reported (inclusion criteria: = >23 weeks)
Study details	Group 1 N = 80 Group Name: Held baby Group 2 N = 18 Group Name: Did not hold the baby
Outcomes	PTSS symptomatology (IES>20)
Study design	Cohort (retrospective)
Source of funding	Grants from the South-Eastern Norway Health Authority, the Oslo University Hospital Scientific Trust and the Norwegian Research Council (grant no.: 160805-V50)
Limitations	Gestational age at loss not reported, response rate of only 27%
Notes	None

1.7.3 HUGHES2002/TURTON2009

Study ID	HUGHES2002/TURTON2009
Bibliographic reference	Hughes P, Turton P, Hopper E, Evans CDH. Assessment of guidelines for good practice in psychosocial care of mothers after stillbirth: a cohort study. The Lancet. 2002;306:114-8. Turton P, Evans C, Hughes P. Long-term psychosocial sequelae of stillbirth: phase II of a nested case-control cohort study. Archives of Womens Mental Health. 2009;12:35-41.
Methods	**Recruitment and inclusion criteria:** Women who had previously experienced a stillbirth after 18 weeks gestation (and had no live children) who were pregnant with another child and attended an antenatal clinic at one of three district general hospitals. All participants were older than 19 years, had a singleton pregnancy, had a partner and spoke good English. Women in treatment for a physical or mental illness or whose stillbirth was the result of an elective termination for abnormality were excluded **Country:** UK
Participants	**Timing:** Unclear (51% conceived less than 12 months after loss and 49% more than 12 months after loss) **N:** 65 **Mean age (years):** At time of participation: 30 **Pregnancy at time of participation:** All of the women were pregnant at time of study **Gestational age at loss:** Not reported (inclusion criteria: >18 weeks)
Study details	Group 1 N = 34 Group Name: Held baby Group 2 N = 31 Group Name: Did not hold the baby Group 3 N = 48

	Group Name: Saw baby Group 4 N = 17 Group Name: Did not see the baby
Outcomes	Depression symptomatology (EPDS>14/BDI>10); Depression mean scores (EPDS/BDI); Anxiety symptomatology (STAI-S>44); Anxiety mean scores (STAI-S); PTSD symptomatology and mean scores (PTSD-1)
Study design	Nested cohort within case-control
Source of funding	South Thames R&D, the Simenauer Trust (Institute of Psycho-Analysis), and by Tommy's Campaign
Limitations	Gestational age at loss not reported
Notes	Continuous data requested from, and supplied by, authors (as Ns not reported in tables in the paper)

1.7.4 RADESTAD2009/ SURKAN2008

Study ID	RADESTAD2009/ SURKAN2008
Bibliographic reference	Rådestad I, Säflund K, Wredling R, Onelöv E, Steineck G. Holding a stillborn baby: mothers' feelings of tenderness and grief. British Journal of Midwifery. 2009;17:178-180. Surkan PJ, Rådestad I, Cnattingius S, Steineck G, Dickman PW. Events after stillbirth in relation to maternal depressive symptoms: a brief report. Birth. 2008;35:153-7.
Methods	**Recruitment and inclusion criteria:** : Swedish population-based Medical Birth Register was used to identify all women who had had a stillborn baby (>28 weeks gestation) in Sweden in 1991, spoken Swedish and had an identified permanent address in Sweden at the time of the study **Country:** Sweden
Participants	**Timing:** 3 years after the stillbirth **N:** 380 identified; data available for 314 **Mean age (years):** Not reported **Pregnancy at time of participation:** Not reported **Gestational age at loss:** Not reported (inclusion criteria: >28 weeks)
Study details	Group 1 N = 203 Group Name: Held baby Group 2 N = 92 Group Name: Did not hold the baby Group 3 N = 263 Group Name: Saw baby Group 4 N = 32 Group Name: Did not see the baby Group 5 N = 207 Group Name: With baby as long as wished

	Group 6 N = 38 Group Name: Not with baby as long as wished Group 7 N = 280 Group Name: Kept a photo of baby Group 8 N = 18 Group Name: Did not keep a photo of baby Group 9 N = 231 Group Name: Kept a token of remembrance Group 10 N = 65 Group Name: Did not keep a token of remembrance Group 11 N = 256 Group Name: Took bromocriptine to stop milk production Group 12 N = 9 Group Name: Did not take bromocriptine to stop milk production
Outcomes	Depression symptomatology (CES-D>90th percentile); Anxiety symptomatology (STAI-S>90th percentile)
Study design	Cohort (retrospective)
Source of funding	Division of Clinical Cancer Epidemiology, Department of Oncology and Pathology, Karolinska Institutet, Stockholm, Sweden
Limitations	Gestational age at loss not reported and significant difference in education level between mothers who held and mothers who did not hold their baby (with a higher education level amongst mothers who held)
Notes	None

1.8 PSYCHOSOCIAL INTERVENTIONS: PROTOCOLS FOR WOMEN FOLLOWING STILLBIRTH – EXCLUDED STUDIES

Study	Reason for exclusion
Crawley R, Lomax S, Ayers S. Recovering from stillbirth: the effects of making and sharing memories on maternal mental health. Journal of Reproductive and Infant Psychology. 2013;31:195-207.	Data cannot be extracted as 100% of the sample saw their baby and 93% held their baby
Rådestad I, Säflund K, Wredling R, Onelöv E, Steineck G. Holding a stillborn baby: mothers' feelings of tenderness and grief. British Journal of Midwifery. 2009;17:178-180.	Data cannot be extracted as 100% of the sample saw their baby and 94% held their baby

1.9 PSYCHOSOCIAL INTERVENTIONS: PREVENTION (NO RISK FACTORS IDENTIFIED) – INCLUDED STUDIES

1.9.1 HOWELL2014

Study ID	HOWELL2014
Bibliographic reference	Howell EA, Bodnar-Derens, Balbierz A, Loudon H, Mora PA, Zlotnick C, et al. An intervention to reduce postpartum depressive symptoms: a randomized controlled trial. Archives of Womens Mental Health. 2014;17:57-63.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital and telephone **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** 13% of sample had EPDS score = >10. Baseline EPDS mean=4.5 (SD 2.8) **N (number randomised):** 540 **Mean age (years):** 32.5 **Inclusion criteria:** i) ≥18 years of age; ii) infants with birth weights ≥2500g; iii) 5-min Apgar scores ≥7; iv) self-identified as white, Asian, or other (non-black and non-Latina as an earlier trial had recruited only black and latina women) **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Behavioural educational intervention **Description:** Two-stage behavioural educational intervention involving a 15-minute in-hospital review of a patient education booklet (describing common postpatrum physical symptoms, dperession, infant colic, and the importance of social support) and a follow-up telephone call (at two weeks post-delivery) which included assessment of symptoms and skills in symptom management and other needs. The intervention was based on the Common-Sense Model (CSM) which targets the interpretative process (between current physical self and expectations about speed of recovery) and addresses the need to bolster social support and personal resources and set realistic time frames for return to normal **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** 1 **Duration (weeks):** 2 **Provider:** Masters-trained social worker **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Enhanced usual care also involved a two-stage process of: routine postpartum hospital education including discharge materials, and television educational programmes on infant care, breastfeeding, and peripartum care; and a follow-up telephone call to inform participants of future surveys. A list of health-related and community resources was also mailed to control participants **Format:** Individual

	Group size: N/A **Sessions:** 2 **Frequency (number of doses per week):** N/A **Duration (weeks):** 2 **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS=>10) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Mental Health (5R01MH77683) and the National Institute on Minority Health and Health Disparities (5P60MD000270)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as data not reported for secondary outcomes (breastfeeding continuation and physical functioning)
Notes	Protocol registered: NCT00951717

1.9.2 KALINAUSKIENE2009

Study ID	KALINAUSKIENE2009
Bibliographic reference	Kalinauskiene L, Cekuoliene D, Van Ijzendoorn MH, Bakermans-Kranenburg MJ, Juffer F, Kusakovskaja I. Supporting insensitive mothers: the Vilnius randomized control trial of video-feedback intervention to promote maternal sensitivity and infant attachment security. Child: care, health and development. 2009;35:613–623.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Home **Country:** Lithuania
Participants	**Timing:** Postnatal **Baseline symptoms:** 'Insensitive' mothers (classified as score<5 [midpoint] on Ainsworth rating scale for sensitivity) **N (number randomised):** 54 **Mean age (years):** 26.4 **Inclusion criteria:** i) Mothers and their first-born infants; ii) mothers from intact families, who were primary caregivers to their infants; iii) mothers who did not work until their children reached 12 months of age; iv) mothers with at least high school education; v) mothers classified as 'insensitive' during free play with their infant at 6 months (defined as score<5 [midpoint] on Ainsworth rating scale for sensitivity) **Exclusion criteria:** i) Mothers or infants with serious health problems
Interventions	**Experimental intervention** **Name:** Video-feedback intervention to promote positive parenting (VIPP) **Description:** Video-feedback intervention to promote positive parenting (VIPP) in mothers who were classified as 'insensitive' at baseline (defined as score<5 [midpoint] on Ainsworth rating scale for sensitivity). In each session mother-child interactions were videotaped and feeedback was given based on the video recorded at the previous session. The main goal of the intervention

	was to reinforce mothers' sensitivity to their infants' signals. Mothers were also provided with brochures about sensitive parenting. Each intervention session focused on a different topic: the baby's contact seeking, playing, exploration and crying behaviour and possible reactions to it, understanding the feelings of the baby, sensitive responsiveness to the baby's signals, and sharing emotions **Format:** Individual **Group size:** N/A **Sessions:** 5 **Frequency (number of doses per week):** 0.2 **Duration (weeks):** 22 **Provider:** Not reported **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Mothers were contacted by phone monthly for 5 months, and asked for information on their infants' development. No advice about sensitive parenting or attachment was given to the control group mothers during these conversations **Format:** N/A **Group size:** N/A **Sessions:** 5 **Frequency (number of doses per week):** 0.2 **Duration (weeks):** 22 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression mean scores (BDI); Maternal sensitivity (Ainsworth); Infant attachment-security (AQS); maternal confidence/competence (PEQ); Maternal stress (Daily Hassles Scale) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Vilnius Municipality, Health Department, and the Netherlands Organization for International Cooperation in Higher Education for their support to the first author. Support from the Netherlands Organization for Scientific Research to the third author (NWO SPINOZA Prize) and to the fourth author (NWO VIDI grant) is gratefully acknowledged.We also acknowledge the financial support received from Wereldkinderen to Femmie Juffer.
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.9.3 LAVENDER1998

Study ID	LAVENDER1998
Bibliographic reference	Lavender T, Walkinshaw SA. Can midwives reduce postpartum psychological morbidity? A randomized trial. Birth. 1998;25:215-219.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the

	participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self report **Setting:** Hospital **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 120 **Mean age (years):** 24.2 **Inclusion criteria:** i) Primigravidas with singleton pregnancies and cephalic presentations who were in spontaneous labour at term and proceeded to have a normal vaginal delivery of a healthy baby **Exclusion criteria:** i) Third-degree perineal tear; ii) manual removal of placenta; iii) neonatal intensive care unit admission; iv) high dependency maternity care.
Interventions	**Experimental intervention** **Name:** Debriefing **Description:** An interactive interview in which mothers spent as much time as necessary discussing their labour, asking questions and exploring their feelings. One research midwife (with no formal training in counselling) conducted the interviews. Women were encouraged to speak freely and openly about their experience and to discuss its positive and negative aspects **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** N/A **Duration (weeks):** Single session **Provider:** Research midwife **Control intervention** **Name:** Treatment as usual **Description:** Standard care. Effort was made not to encourage any childbirth discussions **Format:** N/A **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** N/A **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (HAD=>11); Anxiety symptomatology (HAD=>11) **Outcomes not used:** Drop-out cannot be extracted as not split by group
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.9.4 MORRELL2000

Study ID	MORRELL2000
Bibliographic reference	Morrell CJ, Spiby H, Stewart P, Walters S, Morgan A. Costs and effectiveness of community postnatal support workers: randomised controlled trial. BMJ. 2000;321:593-598.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self report **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 623 **Mean age (years):** 27.8 **Inclusion criteria:** i) aged 17 years or over; ii) delivered a live baby; iii) lived in the area served by community midwives at the recruiting hospital **Exclusion criteria:** i) Baby in special care unit for >48 hrs; ii) women who could not give informed consent or communicate in English
Interventions	**Experimental intervention** **Name:** Community postnatal support worker visits **Description:** Practical and emotional support, including helping the mother rest and recover after childbirth, gain confidence in caring for her baby and reinforcing midwifery advice on infant feeding and helping with housework (in addition to standard midwife visits). The length of visits ranged from 10 to 375 minutes, with most time spent on housework (38%), talking with the mother (23%), dealing with the baby (9%), dealing with other siblings (8%), bottle feeding (7%), talking about the baby (6%), and discussing breast feeding (3%) **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 2.8 **Duration (weeks):** 4 **Provider:** Community support workers **Control intervention** **Name:** Treatment as usual **Description:** Postnatal care at home by community midwives **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4 **Provider:** Community midwives
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (EPDS); General mental health (SF-36 MCS); Social support (DESS); Mother-infant (discontinued breastfeeding) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	NHS Research and Development, Health Technology Assessment programme

Limitations	1. High risk of selection bias due to statistically significant baseline group differences for incidence of twins, use of TENS during labour, and adults living with the mother 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.9.5 MORRELL2009A/2009B/2011/BRUGHA2011

Study ID	MORRELL2009A/2009B/2011/BRUGHA2011
Bibliographic reference	Morrell CJ, Warner R, Slade P, Dixon S, Walters S, Paley G, et al. Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial. Health Technology Assessment. 2009a;13:No. 30. Morrell CJ, Slade P, Warner R, Paley G, Dixon S, Walters SJ, et al. Clinical effectiveness of health visitor training in psychologically informed approaches for depression in postnatal women: pragmatic cluster randomised trial in primary care. BMJ. 2009b;338:a3045. Morrell CJ, Ricketts T, Tudor K, Williams C, Curran J, Barkham M. Training health visitors in cognitive behavioural and person-centred approaches for depression in postnatal women as part of a cluster randomised trial and economic evaluation in primary care: the PoNDER trial. Primary Health Care Research and Development. 2011;12:11-20. Brugha TS, Morrell CJ, Slade P, Walters SJ. Universal prevention of depression in women postnatally: cluster randomized trial evidence in primary care. Psychological Medicine. 2011;41:739-748.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self report **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Baseline EPDS in 'all women' (total sample)=6.7 (4.8) **N (number randomised):** 3449 **Mean age (years):** 31.5 **Inclusion criteria:** i) Antenatal women registered with participating practices in the Trent region; ii) aged 18 or more; able to give informed consent **Exclusion criteria:** i) severe mental health problems.
Interventions	**Experimental intervention 1** **Name:** Cognitive behavioural approach **Description:** The cognitive behavioural training emphasised a normalising rationale and the identification of unhelpful patterns of behaviours, perceptions or thoughts in the owman's life, in order to help the woman to

	change these herself **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Health visitor **Experimental intervention 2** **Name:** Person centred approach **Description:** The person-centred training used the three principles of the actualising tendency, a non-directive attitude and the necessary and sufficient conditions of change. PCA was based on the idea that opportunities to explore difficulties with another, who listens non-judgementally and reflects empathically, allows a person to feel validated as a person and facilitates their abilities to manage their distress and find their own solutions. **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Health visitor **Control intervention** **Name:** Treatment as usual **Description:** General practitioners, midwives, and hospital obstetricians meet women early in pregnancy to plan care. Care is then given by a midwife, shared between the midwife and possibly a general practitioner, or otherwise. Consultant led care is based on clinical need. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8 **Provider:** General practitioners, midwives, and hospital obstetricians (according to individual need)
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS=>12); mean score (EPDS); physical health (SF-12 PCS); general mental health (SF-12 MCS); wellbeing (CORE-OM); risk of self-harm (CORE-OM); life functioning (CORE-OM); anxiety (STAI); parental stress (PSI) **Outcomes not used:** 12- and 18-month follow-up data not reported. Data not extracted for CORE-OM symptoms (or CORE-OM total score) as SF-12 MCS also reported and this is more widely used measure of general mental health, data also not extracted for SF-6D as not clear what this outcome measures. Data not extracted for SF-12 PCS as outcome outside scope. Life Events Questionnaire (LEQ) not used. PSI subscales not extracted as total score more widely reported
Study design	Randomised controlled trial (RCT)
Source of funding	NHS research and development health technology assessment programme
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear/unknown as paper reports available case, and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures

	3. High risk of selective reporting bias as 12- and 18-month outcome data are not reported
Notes	Protocol registered: ISRCTN92195776 This study also provides outcomes for Treatment-Symptoms (see below)

1.9.6 PEREZBLASCO2013

Study ID	PEREZBLASCO2013
Bibliographic reference	Perez-Blasco J, Viguer P, Rodrigo MF. Effects of a mindfulness-based intervention on psychological distress, well-being, and maternal self-efficacy in breast-feeding mothers: results of a pilot study. Archives of Womens Mental Health. 2013;16:227–236.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self report **Setting:** Clinic (primary) **Country:** Spain
Participants	**Timing:** Postnatal **Baseline symptoms:** Not reported **N (number randomised):** 26 **Mean age (years):** 34.3 **Inclusion criteria:** Not reported **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Mindfulness-based intervention **Description:** Mindfulness training based on Mindfulness-Based Stress Reduction (MBSR), Mindfulness-Based Cognitive Therapy (MBCT) and Mindful Self-compassion (MSC) programmes. Modifications were made to the organization and content of the intervention to make it more appropriate for the postnatal period. Namely, babies remained in the room during sessions and instead of having one 30-minute meditation per session, there were 2-3 10-minute meditations. All sessions included: Review of the tasks performed during the previous week; Brief guided meditations (following basic guidelines of MBSR, MBCT, and MSC: Breathing, the Now, Letting Go, Body Scan, the Mountain, the Lake, Compassion, Goals, Forgiveness); Introduction to and discussion of central themes in mindfulness practice in relation to personal maternity and parenting experiences; Formal and informal homework tasks were assigned including a daily activity related to mindful parenting. Due to their parenting demands, almost all participants found it difficult to find time to practice formal meditation and a lot of group session time involved the sharing of strategies to overcome that challenge **Format:** Group **Group size:** Not reported **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Not reported **Control intervention**

	Name: Waitlist **Description:** Women in the control group received no interventions of any kind during the study but were told they would receive two mindfulness meditation sessions once post-test measures were complete **Format:** N/A **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 8 **Provider:** N/A
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (DASS); Anxiety mean scores (DASS); General mental health (DASS); Parenting stress (DASS); Quality of life (satisfaction with life, happiness); Maternal self-efficacy (Parental Evaluation Scale) **Outcomes not used:** Data not extracted for the Five Facet Mindfulness Questionnaire or the Self-Compassion Scale
Study design	Randomised controlled trial (RCT)
Source of funding	Amamanta Association and the San Marcelino Health Center (Valencia, Spain)
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.9.7 TSENG2010

Study ID	TSENG2010
Bibliographic reference	Tseng Y-F, Chen C-H, Lee CS. Effects of listening to music on postpartum stress and anxiety levels. Journal of Clinical Nursing. 2010;19:1049-1055.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self report **Setting:** Home **Country:** Taiwan
Participants	**Timing:** Postnatal **Baseline symptoms:** Without diagnosis **N (number randomised):** 92 **Mean age (years):** 30.6 **Inclusion criteria:** i) at least 18 years old and married; ii) delivery of a mature and normal newborn; iii) consent to participate **Exclusion criteria:** i) Postnatal women who had apparent postpartum complications or an illness requiring prescription medication
Interventions	**Experimental intervention** **Name:** Postnatal music therapy

	Description: Women agreed to listen to at least one CD (spend at least half an hour) a day for two weeks listening to music. Four CDs were used including lullabies, classical music, nature sounds, or children's rhymes and songs. Investigators suggested that women could listen to the music while they were resting, at bedtime or while performing chores **Format:** Individual **Group size:** N/A **Sessions:** 0 sessions of contact with healthcare professional (14 CD sessions) **Frequency (number of doses per week):** 7 **Duration (weeks):** 2 **Provider:** Self (CD) **Control intervention** **Name:** Treatment as usual **Description:** Standard postpartum care **Format:** Not reported **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Anxiety mean scores (STAI); Parental stress (PSS) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Grant NSC 92-2314-B-037-005 from the National Science Council, Taipei, Taiwan.
Limitations	1. High risk of selection bias as allocation concealment is unclear and statistically significant group difference at baseline in education (intervention group were more highly educated than control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.10PSYCHOSOCIAL INTERVENTIONS: PREVENTION (NO RISK FACTORS IDENTIFIED) – EXCLUDED STUDIES

Study	Reason for exclusion
Ammaniti M, Speranza AM, Tambelli R, Muscetta S, Lucarelli L, Vismara L, et al. A prevention and promotion intervention program in the field of mother-infant relationship. Infant Mental Health Journal. 2006;27:70-90.	No mental health outcome reported
Bogaerts AFL, Devlieger R, Nuyts E, Witters I, Gyselaers W, Van den Bergh BRH. Effects of lifestyle intervention in obese pregnant women on gestational weight gain and mental health: a randomized controlled trial. International Journal of Obesity. 2013;37:814-821.	Data cannot be extracted for mental health outcomes
Carty EM, Bradley CF. A randomized, controlled evaluation of early postpartum hospital discharge. Birth, 17, 199-204.	Outside scope (organisation of care)
Chang M-Y, Chen C-H, Huang K-F. Effects of music therapy on psychological health of women during pregnancy. Journal of Clinical Nursing. 2008;17:2580-2587.	Not culturally relevant
Chuang LL, Lin LC, Cheng PJ, Chen CH, Wu SC, Chang CL. Effects of a relaxation training programme on immediate and prolonged stress responses in women with preterm labour. Journal of Advanced Nursing. 2012;68:170-180.	Group allocation was not randomised
Christie J, Bunting B. The effect of health visitors' postpartum home visit frequency on first-time mothers: cluster randomised trial. International Journal of Nursing Studies. 2011;48:689-702.	Intervention not relevant
Cyna AM, Crowther CA, Robinson JS, Andrew MI, Antoniou G, Baghurst P. Hypnosis antenatal training for childbirth: a randomised controlled trial. BJOG. 2013;120:1248–1259.	No mental health outcome reported
Feinberg ME, Kan ML. Establishing family foundations: intervention effects on coparenting, parent/infant well-being, and parent-child relations. Journal of Family Psychology. 2008;22:253-263.	Data cannot be extracted (Ns not reported in table)
Gedde-Dahl M, Fors EA. Impact of self-administered relaxation and guided imagery techniques during final trimester and birth. Complementary Therapies in Clinical Parctice. 2012;18:60-65.	No mental health diagnosis and no mental health outcomes
Guse C, Wissing MP, Hartman W. The effect of a prenatal hypnotherapeutic programme on postnatal maternal psychological well-being. Journal of Reproductive and Infant Psychology. 2006;24:163-177.	Group allocation was not randomised (participants were randomly assigned to the experimental [n=23] and control [n=23] groups except for eight women who were willing to participate in the study but could not take part in the intervention programme due to work responsibilities, and were then assigned to the control group)
Hayes BA, Muller R. Prenatal depression: a randomized controlled trial in the emotional health of primiparous women. Research and Theory for Nursing Practice. 2004;18:165-183.	Paper unavailable
Hayes BA, Muller R, Bradley BS. Perinatal depression: a randomized controlled trial of an antenatal education intervention for primiparas. Birth. 2001;28:28-35.	Data cannot be extracted (only medians and IQRs reported)

Jareethum R, Titapant V, Chantra T, Sommai V, Chuenwattana P, Jirawan C. Satisfaction of healthy pregnant women receiving short message service via mobile phone for prenatal support: a randomized controlled trial. Journal of the Medical Association of Thailand. 2008;91:458-463.	Paper unavailable
Lumley J, Watson L, Small R, Brown S, Mitchell C, Gunn J. PRISM (Program of Resources, Information and Support for Mothers): a community-randomised trial to reduce depression and improve women's physical health six months after birth. BMC Public Health. 2006;6:38.	Outside scope (organisation of care)
Mao H-J, Li H-J, Chiu H, Chan Q-C, Chen S-L. Effectiveness of antenatal emotional self-management training program in prevention of postnatal depression in Chinese women. Perspectives in Psychiatric Care. 2012;48:218-224.	Not culturally relevant
Matthey S, Crncec R. Comparison of two strategies to improve infant sleep problems, and associated impacts on maternal experience, mood and infant emotional health: a single case replication design study. Early Human Development. 2012;88:437-442.	Data cannot be extracted
MacArthur C, Winter H, Bick D, Henderson C, Knowles H. Re-designed community postnatal care trial. British Journal of Midwifery. 2005;13:319-324.	Outside scope (organisation of care)
Middlemiss C, Dawson AJ, Gough N, Jones ME, Coles EC. A randomised study of a domiciliary antenatal care scheme: maternal psychological effects. Midwifery. 1989;5:69-74.	Outside scope (organisation of care)
Niccols A. 'Right from the start': randomized trial comparing an attachment group intervention to supportive home visiting. Journal of Child Psychology and Psychiatry and Allied Disciplines. 2008;49:754-764.	Aim of intervention not relevant
Paul IM, Beiler JS, Schaefer EW, Hollenbeak CS, Alleman N, Sturgis SA, et al. A randomized trial of single home nursing visits vs office-based care after nursery/maternity discharge: the Nurses for Infants through Teaching and Assessment after the Nursery (NITTANY) study. Archives of Pediatrics and Adolescent Medicine. 2012;166:263-270.	Outside scope (organisation of care)
Priest SR, Henderson J, Evans SF, Hagan R. Stress debriefing after childbirth: a randomised controlled trial. Medical Journal of Australia. 2003;178:542-545.	Outcome measure not assessed for all participants (only those who met criteria were assessed)
Reid M, Glazener C, Murray GD, Taylor GS. A two-centred pragmatic randomised controlled trial of two interventions of postnatal support. BJOG. 2002;109:1164-1170.	Disagreggated data could not be extracted (data are pooled across groups and it's impossible to diaggregate what is being compared with what; can't combine groups because double-count participants, therefore the only comparisons we could make are 'support group, and support group and pack combined' versus 'no treatment and pack' and 'pack, and support group and pack combined' versus 'no treatment and support group'- which do

	not inform us about effect of the intervention)
Selkirk R, McLaren S, Ollerenshaw A, McLachlan AJ. The longitudinal effects of midwife-led postnatal debriefing on the psychological health of mothers. Journal of Reproductive and Infant Psychology. 2006;24:133-147.	Group allocation was not randomised (paper reports "Each participant's completed consent form was numbered as it arrived. Those participants with an odd number were allocated to the treatment group, and those participants with an even number were allocated to the control group")
Shields N, Reid M, Cheyne H, Holmes A, McGinley M, Turnbull D, et al. Impact of midwife-managed care in the postnatal period: an exploration of psychosocial outcomes. Journal of Reproductive and Infant Psychology. 1997;15:91-108.	Outside scope (organisation of care)
Tang YF, Shi SX, Lu W, Chen Y, Wang QQ, Zhu YY. Prenatal psychological prevention trial on postpartum anxiety and depression. Chinese Mental Health Journal. 2009;23:83-89.	Paper unavailable
Tripathy P, Nair N, Barnett S, Mahapatra R, Borghi J, Rath S, et al. Effect of a participatory intervention with women's groups on birth outcomes and maternal depression in Jharkhand and Orissa, India: a cluster-randomised controlled trial. Lancet. 2010;375:1182-1192.	Not culturally relevant
Waldenström U, Brown S, McLachlan H, Forster D, Brennecke S. Does team midwife care increase satisfaction with antenatal, intrapartum, and postpartum care? A randomized controlled trial. Birth. 2000;27:156-167.	Outside scope (organisation of care)
Yang M, Li L, Zhu H, Alexander IM, Liu S, Zhou W, et al. Music therapy to relieve anxiety in pregnant women on bedrest: a randomized, controlled trial. American Journal of Maternal Child Nursing. 2009;34:316-323.	Not culturally relevant

1.11 PSYCHOSOCIAL INTERVENTIONS: TREATMENT – INCLUDED STUDIES

1.11.1 AMMERMAN2013A/2013B

Study ID	AMMERMAN2013A/2013B
Bibliographic reference	Ammerman RT, Putnam FW, Altaye M, Stevens J, Teeters AR, Van Ginkel JB. A clinical trial of in-home CBT for depressed mothers in home visitation. Behaviour Therapy. 2013a; 44:359-72 Ammerman RT, Putnam FW, Altaye M, Teeters AR, Stevens J, Van Ginkel JB. Treatment of depressed mothers in home visiting: impact on psychological distress and social functioning. Child Abuse and Neglect. 2013b;37:544-554.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** Current diagnosis of MDD (SCID-I). Baseline BDI-II: 33.8 (SD 7.1). Baseline EPDS: 19.0 (SD 2.8). Baseline HDRS: 21.9 (SD 3.1) **N (number randomised):** 93 **Mean age (years):** 21.9 **Inclusion criteria:** i) women enrolled in a home visitation programme; ii) ≥16 years of age; iii) EPDS=>11; iv) current DSM-IV diagnosis of MDD (determined using SCID-I); v) at least one of the following risk factors: unmarried, low inclome, = <18 years, inadequate prenatal care **Exclusion criteria:** i) Bipolar disorder; ii) Current substance dependence; iii) psychosis; iv) mental retardation; V) suicidality, or homicidality requiring acute intervention; vi) current use of psychotropic medications or psychotherapy
Interventions	**Experimental intervention** **Name:** In-Home CBT + Home visiting **Description:** Mothers in the IH-CBT condition received IH-CBT + home visiting (see home visiting below). The focus and content of treatment followed the directives of CBT (Beck, 2011). The primary target of treatment was depression reduction. Treatment components included behavioral activation, identification of automatic thoughts and schemas, thought restructuring, and relapse prevention. Significant adaptations to CBT were made to address setting (delivered in-home), population (addressing primary concerns of young, low-income, new mothers who were socially isolated), and context (additional contextual and developmental issues incorporated into treatment, such as school attendance and living with parents, and facilitate close collaboration with health visitors) in order to maximize engagement and outcomes. These adaptations were made based upon a review of the literature, consultation with home visitors, and input from mothers in home visitation. **Format:** Individual **Group size:** N/A **Sessions:** 11 **Frequency (number of doses per week):** 1

	Duration (weeks): 15 **Provider:** Licensed social worker **Control intervention** **Name:** Standard Home visiting **Description:** Regular home visits during the trial, and home visitors are given discretion to increase frequency of visits if needed. Mothers received services from home visitors as per the Healthy Families America (HFA; 87%) and Nurse-Family Partnership (NFP; 13%) model directives. Curricula for both models are distinct but emphasize child health and development, nurturing mother-child relationship, maternal health and self-sufficiency, and linkage to other community services. Consistent with standard of care, mothers in the SHV condition were permitted to receive treatment for depression in the community. **Format:** Individual **Group size:** N/A **Sessions:** 14 **Frequency (number of doses per week):** Not reported **Duration (weeks):** 15 **Provider:** Nurse or social worker
Outcomes	**Outcomes used:** Depression diagnosis (SCID-I); Depression mean scores (EPDS); Life functioning (GAF); General mental health (BSI); Social support (ISEI); Drop-out **Outcomes not used:** Data was not used for the Outside Treatment Tracking Form (OTTF); Consumer Satisfaction; BDI-II or HDRS as EPDS more widely reported measure for depression mean scores; Social Network Index (SNI) as ISEI more widely reported measure of social support; Data not used for subscales of BSI or ISEI
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH Grant R34MH073867
Limitations	1. Risk of selection bias is unclear/unknown as randomisation method is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.2 ARMSTRONG1999 /ARMSTRONG2000/FRASER2000

Study ID	AMMERMAN2013A/2013B
Bibliographic reference	Armstrong KL, Fraser JA, Dadds MR, Morris J. A randomized, controlled trial of nurse home visiting to vulnerable families with newborns. Journal of Paediatric Child Health. 1999;35:237-244. Armstrong KL, Fraser JA, Dadds MR, Morris J. Promoting secure attachment, maternal mood and child health in a vulnerable population: a randomized controlled trial. Journal of Paediatric Child Health. 2000;36:555-562. Fraser JA, Armstrong KL, Morris JP, Dadds MR. Home visiting intervention for vulnerable families with newborns: follow-up results of a randomized

	controlled trial. Child Abuse & Neglect. 2000;24:1399-1429.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinding of outcome assessor unclear **Setting:** Home **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 23% EPDS>12. Baseline EPDS mean=8.7 (SD 3.5) **N (number randomised):** 181 **Mean age (years):** 26.2 **Inclusion criteria:** i) Women in the immediate postnatal period; ii) had at least one liveborn infant; iii) were literate and able to complete questionnaires in English with some asssitance; iv) planned to reside in Brisbane's northern suburbs; v) were regarded as high risk. High risk was defined at two levels: a) at least one of the following four: sole parenthood; ambivalence to the pregnancy (sought termination, no antenatal care); physical forms of domestic violence; childhood abuse of either parent; b) three or more of the following: maternal age<18 years old; unstable housing (3 or more moves in 2 years, homelessness); financial stress (often concerned about enough food or making ends meet); maternal education<10 years; low family income (<$16,000 per annum); social isolation; history of mental health disorder (either parent); alcohol or drug abuse; domestic violence other than physical abuse **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Child health nurse visits **Description:** Structured programme of weekly child health nurse visits. The focus of the programme was to: i) establish a relationship of trust with the infant's family; ii) enhance parenting self-esteem and confidence by reinforcement of success; iii) provide anticipatory guidance for normal child development problems such as crying or sleep behaviour variants; iv) promote preventative child health care; and v) facilitate access to appropriate community services. **Format:** Individual **Group size:** N/A **Sessions:** 18 **Frequency (number of doses per week):** Variable (weekly for the first 6 weeks, fortnightly until 3 months, then monthly until the age of 12 months) **Duration (weeks):** 52 **Provider:** Child health nurse **Control intervention** **Name:** Treatment as usual **Description:** Optional community child health centre attendance **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Variable (as per individual need) **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS>12); Depression mean scores (EPDS); Parental stress (PSI); Prevention of abuse and

	neglect (CAPI; poison ingestion); Optimal care of infant (HOME environment; immunisation) **Outcomes not used:** Data not extracted from ARMSTRONG1999 or ARMSTRONG2000 as mid-treatment
Study design	Randomised controlled trial (RCT)
Source of funding	Community Child Health Services, Royal Children's Hospital and District Health Service, National health and Medical Research Council of Australia
Limitations	1. High risk of selection bias due to statistically significant baseline group differences in: parity (54% of intervention group primiparous versus 33% of control); identification as indigenous Australian (9% of intervention versus 2% of control); mental illness of partner (3% of intervention versus 14% of control); history of postnatal depression (11% of intervention versus 28% of control); physical domestic abuse (2% of intervention versus 10% of control); potential for child abuse (mean CAPI score in intervention was 123 versus 159 in control, and elevated CAPI score for 12% of intervention group versus 30% of control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of detection bias is unclear/unknown for the Home Observation for Measurement of the Environment Inventory (HOME) outcome measure as blinding of outcome assessor is unclear 4. Risk of bias associated with the analysis method is unclear/unknown as paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 5. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.3 ARMSTRONG2003

Study ID	ARMSTRONG2003
Bibliographic reference	Armstrong K, Edwards H. The effects of exercise and social support on mothers reporting depressive symptoms: a pilot randomized controlled trial. International Journal of Mental Health Nursing. 2003;12:130-138.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Community **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS=>12. Mean baseline EPDS: 17.9 (SD 3.4) **N (number randomised):** 20 **Mean age (years):** Not reported **Inclusion criteria:** i) Living in the Gold Coast region of Queensland; ii) have a child aged 6 weeks to 12 months; iii) EPDS score = >12 **Exclusion criteria:** i) Had a medical condition that would prevent regular aerobic exercise

Interventions	**Experimental intervention** **Name:** Pram walking with informal gathering **Description:** A combined exercise and social support intervention. The exercise component of the intervention involved the participant walking three times per week with the group for 30–40 minutes at a moderated intensity. Participants were encouraged to attend all three pram walking sessions on a Monday, Wednesday and Friday at 9.30 am at a point that was central to the catchment area and had flat walking paths suitable to push a pram. If for unforeseen circumstances a participant was unable to make a session, they were encouraged to make up the session independently and record it in their exercise diary. After the sessions on Mondays an informal gathering (morning tea provided) for a chat and play with the children was encouraged. This was conducted at the nearby local primary school hall. The chief investigator was present at the walking and support sessions. **Format:** Group **Group size:** Not reported **Sessions:** 48 **Frequency (number of doses per week):** 4 **Duration (weeks):** 12 **Provider:** Not reported **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Phone support was provided to control participants at week 6 and participants were encouraged to contact the researchers if they had any concerns **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 12 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS>12 [unpublished data supplied to pevious guideline]);Depression mean scores (EPDS); General mental health (GHQ); Social support (SSI); Drop-out **Outcomes not used:** Data not extracted for 6-week follow-up as mid-treatment. Data not extracted for Depression Anxiety Stress Scale (DASS) as EPDS more widely reported. Data not extracted for physical fitness outcomes (Physical Activity Research Questionnaire [PAR-Q]; fitness test; Borg's perceived level of exertion scale)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	Author supplied dichotomous depression data and dropout clarification to 2007 guideline team

1.11.4 ARMSTRONG2004

Study ID	ARMSTRONG2004

Bibliographic reference	Armstrong K, Edwards H. The effectiveness of a pram-walking exercise programme in reducing depressive symptomatology for postnatal women. International Journal of Nursing Practice. 2004; 10:177-194.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Community **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS mean (SD): pram-walking group (n=9) 17.25 (4.00); support group (n=10) 17.17 (4.45) **N (number randomised):** 24 **Mean age (years):** Not reported **Inclusion criteria:** i) Living in the Gold Coast region of Queensland; ii) have a child aged 6 weeks to 12 months; iii) EPDS score = >12 **Exclusion criteria:** i) Had a medical condition that would prevent regular aerobic exercise
Interventions	**Experimental intervention** **Name:** Social support group **Description:** Unstructured discussion for social and emotional but not practical support. Baby/child welcome. **Format:** Group **Group size:** Not reported **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Nurse/social worker **Control intervention** **Name:** Pram walking exercise programme **Description:** Pram-walking towards target heart-rate; muscle stretches **Format:** Group **Group size:** Not reported **Sessions:** 24 **Frequency (number of doses per week):** 2 **Duration (weeks):** 12 **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (EPDS); Social support (SSI) **Outcomes not used:** Data not extracted for 6-week follow-up as mid-treatment. Data not extracted for physical fitness outcomes
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with analysis method as paper reports available case and not possible to compute ITT (WCS) 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.5 AUSTIN2008

Study ID	AUSTIN2008
Bibliographic reference	Austin M-P, Frilingos M, Lumley J, Hadzi-Pavlovic D, Roncolato W, Acland S, et al. Brief antenatal cognitive behaviour therapy group intervention for the prevention of postnatal depression and anxiety: a randomised controlled trial. Journal of Affective Disorders. 2008;105:35-44.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Not reported **Country:** Australia
Participants	**Timing:** Antenatal **Baseline symptoms:** Mean EPDS at baseline: 7.8 **N (number randomised):** 277 **Mean age (years):** 31 .4 **Inclusion criteria:** i) pregnant women with an EPDS score >10 and/or a score >23 on the Antenatal Risk Questionnaire [ANRQ], or a reported prior history of depression **Exclusion criteria:** i) Engaging in substance or alcohol abuse; ii) have an organic brain disorder, bipolar disorder or schizophrenia; iii) a childhood history of abuse (physical, emotional or sexual); iv) current suicidal ideation; v) a poor command of English; vi) not able to conceptualise CBT principles, unwilling to engage in an active therapeutic intervention or unsuitable for group rather than individual intervention
Interventions	**Experimental intervention** **Name:** CBT-informed psychoeducation **Description:** The CBT-informed psychoeducation intervention comprised 6 weekly 2-hour sessions (and a later follow-up session) of cognitive behavioural therapy, focusing on the prevention and management of stress, anxiety and low mood in the context of pregnancy and caring for a new baby. This structured program was skills based, largely focused on behavioural strategies and encouraged home task practice each week. Components included education about perinatal anxiety and depression as well as infant needs and behaviour in the first few months of life, pleasant event scheduling, relaxation training, goal setting, problem solving, cognitive strategies to address unhelpful attitudes, assertion skills, and how to develop a broad social support network, including local postnatal support services. To ensure program consistency, the intervention was developed into manual format and led by a clinical psychologist **Format:** Group **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Clinical psychologist and midwife **Control intervention** **Name:** Enhanced Treatment as usual **Description:** A psychoeducation booklet which contained comprehensive

	information regarding risk factors for postnatal anxiety and depression, triggers for postnatal distress, and strategies to prevent and/or manage such problems and a list of local postnatal support services and how to access these services. **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 6 **Provider:** Self
Outcomes	**Outcomes used:** Depression diagnosis (MINI); Anxiety diagnosis (MINI); Drop-out **Outcomes not used:** Data could not be extracted for EPDS or STAI
Study design	Randomised controlled trial (RCT)
Source of funding	Rotary Mental Health Foundation, the National Health and Medical Research Council (Program Grant 222708), the New South Wales Centre for Mental Health
Limitations	1. High risk of selection bias due to unclear randomisation method and allocation concealment and statistically significant group differences at baseline with higher mean EPDS in experimental group (8.16) than control group (6.88) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as EPDS and STAI results were not reported
Notes	Data was requested, and author response is pending, for: Means and standard deviations for all outcomes- including depression (EPDS and MINI) and anxiety (STAI)- at all time points

1.11.6 BERNARD2011

Study ID	BERNARD2011
Bibliographic reference	Bernard RS, Williams SE, Storfer-Isser A, Rhine W, Horwitz SM, Koopman C, et al. Brief cognitive-behavioral intervention for maternal depression and trauma in the neonatal intensive care unit: a pilot study. Journal of Traumatic Stress. 2011;24:230-234.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** Mean BDI-II = 13.2 (score 14-19 = moderate) **N (number randomised):** 56 **Mean age (years):** 32.7 **Inclusion criteria:** i) mothers of infants in the NICU; ii) ≥18 years of age; iii) spoke English and/or Spanish; iv) infants had birthweights >1,000 grams, gestational ages <37 weeks, were born at or transferred to the NICU within 72

	hours of delivery, and were expected to survive **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** CBT-informed psychoeducation **Description:** Intervention was tailored to the specific needs of NICU parents. Each session focused on different CBT-based skills including: education about the NICU and premature infant characteristics, identifying common thoughts of NICU parents, and effective communication strategies with NICU staff; cognitive restructuring to reframe overly negative thoughts related to their infant being in the NICU and identifying positive self-statements; relaxation techniques (deep breathing, progressive muscle relaxation). **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 1.5 **Duration (weeks):** 3 **Provider:** Researcher (RB) and a doctoral-level graduate student **Control intervention** **Name:** Treatment as usual **Description:** Standard care group received typical care for NICU parents including contact with nurses, physicians, social workers, and chaplaincy (if requested). **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** N/A **Provider:** Nurses, physicians, social workers, chaplaincy (if requested)
Outcomes	**Outcomes used:** Depression mean score (BDI-II), PTSD mean score (Davidson Trauma Scale); Drop-out **Outcomes not used:** Data not reported for the Stanford Acute Stress Reaction Questionnaire
Study design	Randomised controlled trial (RCT)
Source of funding	NIH M01 RR00070 for the General Clinical Research Center Program, Stanford University School of Medicine
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data not reported for the Stanford Acute Stress Reaction Questionnaire
Notes	Data was requested, and author response is pending, for: Details of method of randomisation, including sequence generation and allocation concealment

1.11.7BILSZTA2012

Study ID	BILSZTA2012
Bibliographic reference	Bilszta JLC, Buist AE, Wang F, Zulkefli NR. Use of video feedback intervention in an inpatient perinatal psychiatric setting to improve maternal parenting.

	Archives of Women's Mental Health. 2012;15:249-257.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-IV diagnosis of major depresisve disorder. Baseline EPDS mean = 19.5 (SD = 0.7). 7.5% comorbid borderline personality disorder and 2.5% comorbid panic disorder **N (number randomised):** 51 **Mean age (years):** Not reported **Inclusion criteria:** i) DSM-IV diagnosis of major clinical depression or adjustment disorder with anxious or depressed mood; ii) able to read and write English; iii) able to provide informed consent **Exclusion criteria:** i) Diagnosed with a psychotic disorder (that is, bipolar disorder, postpartum psychosis, or schizophrenia)
Interventions	**Experimental intervention** **Name:** Video feedback intervention **Description:** Intervention based on modified concept of secure base/secure haven (Marvin et al., 2002). The purpose of the intervention was to help mothers become better perceivers of their infant's verbal and nonverbal cues, as well as teach them to respond quickly and appropriately to these signals, identify potentially improper responses, and reinforce established sensitive behaviors. The first video session focused on helping mothers understand the importance of mother–infant attachment and how the relationship between mother and infant develops. This also included a discussion of past and present attachment experiences to help increase awareness of insecure mental presentations of attachment. During this initial session, mothers were also asked to reflect on their own emotions toward the baby at different times (that is, while feeding, baby sleeping, interacting with baby, when baby is difficult to settle, separated from baby, etc.). At the conclusion of the first session, mothers were asked to nominate any area of their relationship with their infant they wished to explore. Following sessions involved 10 min of baby play in which the mother was video-taped interacting with her infant in any way she wished. Once completed, the mother reviewed the video with a trained mother–infant therapist and discussed the interaction between her and her infant, particularly behaviors that increased the responsiveness of the infant and possible modifications of behavior to increase interaction with her infant. Particular focus was given to any areas of concern that were raised by the mother at the completion of the first session. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 1 **Duration (weeks):** 3 **Provider:** Senior investigator **Control intervention** **Name:** Verbal feedback intervention **Description:** Same as above but without the video-taping. Discussion-based feedback only.

	Format: Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 1 **Duration (weeks):** 3 **Provider:** Senior investigator
Outcomes	**Outcomes used:** Drop-out; Depression mean score (EPDS); Maternal perception of infant behaviour (NPI); Matrenal confidence (PSCS) **Outcomes not used:** Data was not reported for the Sarason Social Support Questionnaire or the Adult Attachment Scale
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data not reported for the Sarason Social Support Questionnaire or the Adult Attachment Scale
Notes	Data cannot be extracted for TAU arm as assignment to this condition was not random

1.11.8 BURNS2013/PEARSON2013B

Study ID	BURNS2013/PEARSON2013b
Bibliographic reference	Burns A, O'Mahen H, Baxter H, Bennert K, Wiles N, Ramchandani P. A pilot randomised controlled trial of cognitive behavioural therapy for antenatal depression. BMC Psychiatry. 2013;13:33. Pearson RM, O'Mahen H, Burns A, Bennert K, Shepherd C, Baxter H, et al. The normalisation of disrupted attentional processing of infant distress in depressed pregnant women following cognitive behavioural therapy. Journal of Affective Disorders. 2013b;145:208-213.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** UK
Participants	**Timing:** Antenatal **Baseline symptoms:** CIS-R score median = 28.5 (7.7); EPDS median = 18.25 (4.7) **N (number randomised):** 36 **Mean age (years):** 29.2 **Inclusion criteria:** i) Women over 16 years of age; ii) Between 8 and 18 weeks pregnant; iii) screened positive on a 3-question depression screen; iv) Met ICD-10 depression criteria **Exclusion criteria:** i) Currently receiving CBT or any individual or group psychological therapy for depression; ii) Women with a psychotic illness; iii) Women who did not have sufficient command of English to complete the

	questionnaires or benefit from an individual talking therapy without an interpreter
Interventions	**Experimental intervention** **Name:** CBT **Description:** The treatment consisted of three modules: Behavioural Activation (BA), Cognitive Restructuring (CR), Interpersonal Support (IS). All women completed the BA module, which included the use of a functional analytical approach to develop an understanding of behaviours that interfere with meaningful, goal-oriented behaviours and included self-monitoring, identifying 'depressed behaviours', developing alternative goal-oriented behaviours, and scheduling. Because mothers in the qualitative research supporting the development of this manual (O'Mahen et al., 2012) described difficulties with balancing activities, rather than in activation per se, the treatment focused on helping mothers achieve a balance in valued activities. Based on their perinatal case conceptualization, women struggling with depressive cognitions or interpersonal difficulties as core problem also completed the CR module, modified to focus on perinatal specific cognitions (for example, rigid motherhood beliefs) and/or the IS module. The IS module conceptualised interpersonal problems in a functional analytical framework consistent with CBT. The therapist worked with the client to develop alternative interpersonal behaviours (for example, role play). The mCBT manual also included an appendix with perinatal specific materials and skills (for example, labour and delivery, sleep) that could be used as tools to support the work in the other modules. Each week women were asked to complete either written or verbally agreed treatment exercises in-between sessions. **Format:** Individual **Group size:** N/A **Sessions:** 9-12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Two therapists, one with master's level experience and the other with doctoral experience in CBT **Control intervention** **Name:** Treatment as usual **Description:** Usual care from their midwife and GP. For a first time mother this usually included a further 9 appointments with midwives after the booking plus scans (a dating and anomaly scan) or 6 further appointments and scans if they have had previously had a baby. Midwives routinely decide how frequently to meet pregnant women depending on their perceived needs and available resources. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** GP and midwife
Outcomes	**Outcomes used:** Drop-out; Depression diagnosis (CIS-R); Depression mean score (EPDS); General mental health (SF-12 MCS); Mother-infant attachment (PAI); Maternal sensitivity (Attentional bias for distressed infant faces) **Outcomes not used:** Physical health (SF-12 PCS); Health (EQ-5D); Awareness of difference in thinking according to mood (Metacognitive Awareness

	Questionnaire). Continuous data extracted for PHQ-9 and CIS-R but not entered into meta-analysis as EPDS more widley used measure. Data not extracted for mild, moderate and severe depressive episode breakdown (but for overall depression) as other studies do not make this distinction. 33-week follow-up data is not reported for mother-infant outcomes
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute for Health Research, RfPB grant number, PB-PG-1207-15063
Limitations	1. High risk of selection bias due to statistically significant baseline group differences in ethnicity (72% white in intervention group and 94% in control group), married/living as married (72% in intervention group and 56% in control group), house ownership status (11% owner in intervention group and 44% on control group), and history of antidepressant use (56% ever used antidepressants before in the intervention group and 83% in the control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method was unclear as the paper only reports available case analysis, and although ITT (WCS) was computed wherever possible, this was not possible for all outcome measures 4. High risk of selective reporting bias as 33-week follow-up data is not reported for mother-infant outcomes
Notes	Protocol registered: ISRCTN44902048 Data cannot be extracted for TAU arm as assignment to this condition was not random

1.11.9 CHEN2000

Study ID	CHEN2000
Bibliographic reference	Chen C-H, Tseng Y-F, Chou F-H, Wang S-Y. Effects of support group intervention in postnatally distressed women. A controlled study in Taiwan. Journal of Psychosomatic Research. 2000;49:395-399.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** Taiwan
Participants	**Timing:** Postnatal **Baseline symptoms:** Mean BDI = 15.8 (4.9) **N (number randomised):** 64 **Mean age (years):** 29.1 **Inclusion criteria:** i) over 18 years of age; ii) survival of the infant; iii) at least a junior high school education; iv) BDI score above the depression cut-off point of 9/10. **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Support group **Description:** The primary goal of the group was to bring women into contact

	with other women having similar experiences, so they could share problems and conflicts and talk about solutions. Each week a different topic area was given primary emphasis; i) discussion of transition, ii) postnatal stress, iii) communication, iv) life planning. Although if other issues arose these were also discussed **Format:** Group **Group size:** 5-6 **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 4 **Provider:** Registered nurse researcher **Control intervention** **Name:** Treatment as usual **Description:** Routine care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (BDI=>10); Depression mean scores (BDI change scores); Parental stress (PSS change scores); Social support (ISEL change scores); Self-esteem (SEI change scores) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Grant NSC 88-2314-B-037-006 from the National Science Council, Taipei, Taiwan
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method and allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method was unclear as the paper only reports available case analysis, and although ITT (WCS) was computed wherever possible, this was not possible for all outcome measures 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.10 CHO2008

Study ID	CHO2008
Bibliographic reference	Cho HJ, Kwon JH, Lee JJ. Antenatal cognitive-behavioral therapy for prevention of postpartum depression: a pilot study. Yonsei Medical Journal. 2008;49:553-562.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported

	Country: Korea
Participants	**Timing:** Antenatal **Baseline symptoms:** Mean BDI = 22.9 ± 4.1 (CBT) 21.0 ± 8.7 (control) **N (number randomised):** 27 **Mean age (years):** 29 **Inclusion criteria:** i) pregnant women scoring more than 16 points on BDI; ii) diagnosed with depressive disorder (major depressive disorder, dysthymic disorder, depressive disorder NOS) through the Structured Clinical Interview for DSM-IV-I. **Exclusion criteria:** i) Depressive disorders due to alcohol abuse, bipolar disorder, organic brain disorder, and obstetric complications
Interventions	**Experimental intervention** **Name:** CBT **Description:** Cognitive behavioral therapy, focusing on improving depressive mood and dysfunctional marital relationships in the context of pregnancy. To ensure program consistency, CBT intervention was developed into a manual format. The components of CBT included educating participants about depression, scheduling pleasant events, and changing negative automatic thoughts to positive ones. Components of marital intervention consisted of promoting acceptance through better understanding of the personalities of their spouses through MBTI, improving communication skills of I-message training by the professional, and making and exchanging a list of rewarding positive behaviors from their spouses **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** 0.5 **Duration (weeks):** 18 **Provider:** Clinical psychologist **Control intervention** **Name:** Enhanced Treatment as usual **Description:** The control group was educated about depression and strategies to control symptoms of depression in 1 session during the pretest period **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** N/A **Duration (weeks):** Single session **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (BDI=>16); Depression mean score (BDI); Negative thoughts (ATQ); Drop-out **Outcomes not used:** Dyadic communication dissatisfaction or global marital dissatisfaction (Snyder's Marital Satisfaction Inventory-R)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of selection bias due to unclear randomisation method and allocation concealment and statistically significant baseline group differences in negative thoughts (higher mean score in experimental group) 2. High risk of performance bias as it was not possible to blind participants or personnel

	3. Risk of bias associated with the analysis method was unclear as the paper only reports available case analysis, and although ITT (WCS) was computed wherever possible, this was not possible for all outcome measures 4. Risk of selective reporting bias is unclear/unknown
Notes	Data was requested, and author response pending for: Method of randomisation including sequence generation, allocation concealment.

1.11.11 COOPER2003/MURRAY2003

Study ID	COOPER2003/MURRAY2003
Bibliographic reference	Cooper PJ, Murray L, Wilson A, Romaniuk H. Controlled trial of the short- and long-term effect of psychological treatment of post-partum depression. I. Impact on maternal mood. British Journal of Psychiatry. 2003;182:412-419. Murray L, Cooper PJ, Wilson A, Romaniuk H. Controlled trial of the short- and long-term effect of psychological treatment of post-partum depression. 2. Impact on the mother-child relationship and child outcome. British Journal of Psychiatry. 2003;182;420-427.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-III-R major depression disorder by SCID for DSM-III-R **N (number randomised):** 193 **Mean age (years):** 27.7 **Inclusion criteria:** i) primiparous; ii) living within a 15-mile radius of the maternity hospital; iii) English as their first language **Exclusion criteria:** i) Premature delivery; ii) infant abnormality; iii) non-singleton
Interventions	**Experimental intervention 1** **Name:** Relationship/attachment-based (CBT-informed) therapy **Description:** The treatment was primarily directed at problems identified by the mother in the management of her infant (concerning, for example, feeding or sleeping), as well as at observed problems in the quality of the mother–infant interaction. In the context of a supportive therapeutic relationship, the mother was provided with advice about managing particular infant problems, was helped to solve such problems in a systematic way, was encouraged to examine her patterns of thinking about her infant and herself as a mother, and was helped through modelling and reinforcement to alter aspects of her interactional style. **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10

	Provider: Therapist **Experimental intervention 2** **Name:** Non-directive counselling **Description:** Non-directive counselling where women were provided with the opportunity to air their feelings about any current concerns, such as marital problems or financial difficulties, as well as concerns they might raise about their infant. **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10 **Provider:** Therapist **Experimental intervention 3** **Name:** Psychodynamic therapy **Description:** Psychodynamic therapy in which an understanding of the mother's representation of her infant and her relationship with her infant was promoted by exploring aspects of the mother's own early attachment history **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10 **Provider:** Therapist **Control intervention** **Name:** Treatment as usual **Description:** Routine primary care, involving the normal care provided by the primary health care team (that is, general practitioners and health visitors) with no additional input (apart from assessment) from the research team. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 10 **Provider:** GPs and health visitors
Outcomes	**Outcomes used:** Depression symptomatology (EPDS=>12) and diagnosis (SCID); Drop-out; Mother-infant behaviour management problems (maternal report); Mother-infant relationship problems (maternal report); Infant attachment (Ainsworth Strange Situation Procedure) **Outcomes not used:** Data cannot be extracted for continuous infant outcome measures (BSQ; Bayley scale; Rutter A scale; PBCL; McCarthy scale) as median and IQR reported and not mean and sd
Study design	Randomised controlled trial (RCT)
Source of funding	Birthright and the Medical Research Council
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data cannot be extracted for continuous infant outcome measures (BSQ; Bayley scale; Rutter A scale; PBCL; McCarthy scale) as median and IQR reported and not mean and sd

Notes	Data was requested, and author response pending for: Details of allocation concealment to the intervention groups

1.11.12 DENNIS2003

Study ID	DENNIS2003
Bibliographic reference	Dennis C-L. The effect of peer support on postpartum depression: a pilot randomized controlled trial. Canadian Journal of Psychiatry. 2003;48:115-124.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Telephone **Country:** Canada
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% EPDS >9 **N (number randomised):** 42 **Mean age (years):** Not reported **Inclusion criteria:** i) new mothers between 8 and 12 weeks post-partum; ii) aged at least 18 years; iii) able to speak English; iv) had a singleton birth at 37 weeks' gestation or more; v) scored > 9 on the EPDS; vi) resided in the surrounding region; vii) were accessible by a local telephone call. **Exclusion criteria:** i) current use of antidepressant medications; ii) a history of psychotherapy during the previous 12-month period; iii) a history of chronic depression, psychiatric clinical disorder, or postpartum psychosis
Interventions	**Experimental intervention** **Name:** Telephone-based peer support **Description:** A mother-to-mother telephone-based support intervention, entitled "Mothers Helping Mothers with Postpartum Depression". Peer support was defined as a specific type of social support that incorporates informational, appraisal (feedback), and emotional assistance. This lay assistance is provided by volunteer individuals who are not part of the mother's own family or immediate social network but who possess experiential knowledge of the targeted behaviour or stressor (PPD) and similar qualities (such as similar residency, age, socio- economic status, or ethnicity). **Format:** Individual **Group size:** N/A **Sessions:** 0 sessions of contact with healthcare professional **(**5 sessions of contact with peer) **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8 **Provider:** Trained volunteers who were mothers themselves **Control intervention** **Name:** Treatment as usual **Description:** Standard community postpartum care **Format:** Individual **Group size:** N/A **Sessions:** Not reported

	Frequency (number of doses per week): Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS>12); Self-esteem (SES); Parental stress (CCSC): Loneliness (UCLA LS); Drop-out **Outcomes not used:** Data was not extracted for EPDS>9 as 12 is the more widely reported cut-off point. Data was not extracted for 4-week follow-up as this was mid-treatment
Study design	Randomised controlled trial (RCT)
Source of funding	Canadian Institutes for Health Research (CIHR)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.13 DENNIS2009/2010

Study ID	DENNIS2009/2010
Bibliographic reference	Dennis C-L, Hodnett E, Reisman HM, Kenton L, Weston J, Zupancic J, et al. Effect of peer support on prevention of postnatal depression among high risk women: multisite randomised controlled trial. BMJ. 2009;338:a3064. Dennis C-L. Postpartum depression peer support: maternal perceptions from a randomized controlled trial. International Journal of Nursing Studies. 2010;47:560-568.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Telephone **Country:** Canada
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% scored >9 on the EPDS. 39% score >12 on EPDS **N (number randomised):** 701 **Mean age (years):** Not reported **Inclusion criteria:** i) new mothers about two weeks postpartum or less; ii) at least 18 years of age; iii) able to speak English; iv) had a live birth; v) were discharged home from hospital with the mother; vi) scored >9 on the Edinburgh postnatal depression scale **Exclusion criteria:** i) women currently taking antidepressant or antipsychotic drugs.
Interventions	**Experimental intervention** **Name:** Telephone-based peer support **Description:** Standard community postpartum care plus telephone based peer support from a mother with a history and recovery from postpartum depression. Telephone contact was initiated within 48-72 hours of randomisation. Peer support mothers underwent a 4-hour training session **Format:** Individual **Group size:** N/A

	Sessions: 0 sessions of contact with healthcare professional **(**9 sessions of contact with peer) **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Trained volunteers who were mothers themselves **Control intervention** **Name:** Treatment as usual **Description:** Standard community postpartum care including access to services from public health nurses and other providers (mother initiated) and drop in centres **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (SCID); Depression symptomatology (EPDS>12); Depression mean score (EPDS); State anxiety symptomatology (STAI>44); mean state anxiety score (STAI); Service utilisation (antidepressant use; health service use); Loneliness (UCLA LS); Drop-out; EoC [extracted separately] **Outcomes not used:** Data not reported for 24-week follow-up for depression diagnosis (SCID) or anxiety symptomatology (STAI>44)
Study design	Randomised controlled trial (RCT)
Source of funding	Canadian Institutes of Health Research grant number MCT 66874.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports only available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data not reported for 24-week follow-up for depression diagnosis (SCID) or anxiety symptomatology (STAI>44)
Notes	Protocol registered: ISRCTN68337727

1.11.14 DUGGAN2007/CALDERA2007

Study ID	DUGGAN2007/CALDERA2007
Bibliographic reference	Duggan AK, Caldera D, Rodriguez K, Burrell L, Rohde C, Crowne SS. Impact of a statewide home visiting program to prevent child abuse. Child Abuse and Neglect. 2007;31:829–852. Caldera D, Burrell L, Rodriguez K, Crowne SS, Rohde C, Duggan A. Impact of a statewide home visiting program on parenting and on child health and development. Child Abuse and Neglect. 2007;31:829-852.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor

	Setting: Home **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 57% CESD >15 **N (number randomised):** 364 **Mean age (years):** 23.6 **Inclusion criteria:** i) Families who screen positive are assessed for risk using Kempe's Family Stress Checklist (FSC) . Families scoring ≥25 are eligible **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Healthy Families Alaska Program **Description:** Healthy Families Alaska Programme is a voluntary intensive, long-term home visiting programme. Home visitors provided information, made referrals to community resources, helped parents prepare for developmental milestones, screened and referred for developmental delay, and promoted child environmental safety. They also supported positive parent–child interaction via role modelling and reinforcement of positive interactions and parental empathy. Home visitors encouraged parents to establish a medical home for child health care and supported parents in crises. Home visitors were encouraged to use individual family support plans to teach problem-solving related to family-initiated goals. **Format:** Individual **Group size:** N/A **Sessions:** 42 **Frequency (number of doses per week):** Variable (visits are offered weekly for the first 6–9 months and less frequently as the family functioning improved) **Duration (weeks):** 104 **Provider:** Trained home visitors **Control intervention** **Name:** Treatment as usual **Description:** Referred to other parenting and family support programmes **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 104 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (CES-D=>24); General mental health symptomatology (NHI-5<67); Parental stress symptomatology (PSI); Substance/alcohol use (CAGE); Prevention of neglect/abuse (child matreatment reports; use of punishment [CTS]; injuries); Mother-infant attachment (NCAST); Optimal care of infant (HOME environment; well child visits; immunisations); Infant cognitive development (Bayley MDI); Infant emotional development (CBCL) **Outcomes not used:** Data cannot be extracted for continuous outcomes as no SDs reported. Data not extracted for all subscales of Straus's parent-child Conflict Tactics Scale (CTS-PS). Data not extracted for material support or parenting services
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of selection bias due to unclear allocation concealment and

	statistically significant baseline differences in poor psychological resources (37% intervention group versus 50% control) and in prenatal enrollment (41% intervention group and 53% control) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.15 DUGRAVIER2013/GUEDENEY2013

Study ID	DUGRAVIER2013/GUEDENEY2013
Bibliographic reference	Dugravier R, Tubach F, Saias T, Guedeney N, Pasquet B, Purper-Ouakil D, et al. Impact of a manualized multifocal perinatal home-visiting program using psychologists on postnatal depression: the CAPEDP randomized controlled trial. PLoS ONE. 2013;8:e72216. Guedeney A, Wendland J, Dugravier R, Saias T, Tubach F, Welniarz B, et al. Impact of a randomized home-visiting trial on infant social withdrawal in the CAPEDP prevention study. Infant Mental Health Journal. 2013;34:594-601.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Home **Country:** France
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 45% EPDS>11. Mean baseline EPDS=10.8 **N (number randomised):** 440 **Mean age (years):** 22.3 **Inclusion criteria:** i) lived in Paris or its inner suburbs; ii) fluent enough in French to give valid informed consent, benefit from the intervention and participate in assessment sessions; iii) <27 weeks after first day of their last menstrual period at their first assessment interview; iv) registered with the national health insurance scheme or its equivalent for non-French particpants (as required by French law on clinical research); v) first-time mothers; vi) <26 years old; vii) <12 years education, or planning to bring up their child without the child's father, or had low income (defined as being eligible for French national social welfare health insurance or Government Medical Aid) **Exclusion criteria:** i) women who were going to be impossibel to follow-up (for example planning to move away after child born); ii) women receiving social or medical care for reasons other than those listed in the inclusion criteria (such as substance abuse, serious mental illness, or other chronic diseases requiring close follow-up); iii) women who did not consent to participate
Interventions	**Experimental intervention** **Name:** Manualized multifocal perinatal home-visiting program **Description:** The manualized home visiting intervention was specifically tailored to empower mothers in terms of developing parenting skills, using the health and social care system, and making the most of their personal networks and local community services. A team of home-visiting psychologists was

	specifically trained to promote mental health and attachment quality, provide social and emotional support within a solid working alliance, and address depression should it occur. **Format:** Individual **Group size:** N/A **Sessions:** 7 **Frequency (number of doses per week):** 0.6 **Duration (weeks):** 22 **Provider:** Psychologist **Control intervention** **Name:** Treatment as usual **Description:** Usual care involved access to the mother-child support and prevention services (PMI) and community mental health networks with no out-of-pocket payment, free antenatal maternity screenings, and a variety of social benefits **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 22 **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS>11); Depression mean score (EPDS); Infant social withdrawal (ADBB) **Outcomes not used:** Data not reported for depression outcomes at 6, 12, 18 or 24 month postpartum assessments. Data not extracted for the Modified ADBB scale as scale not yet validated
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the National Ministry of Health Hospital Clinical Research Programme (PHRC AOM 05056) and the National Institute for Promotion and Health Education. The sponsor was the Clinical Research and Development Department of the APHP
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports modified ITT (at least 1 assessment visit during 12 months after inclusion) but essentially available case, and although ITT (WCS) was computed wherever possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data not reported for depression outcomes at 6, 12, 18 or 24 month postpartum assessments
Notes	Protocol registered: NCT0039284

1.11.16 ELMOHANDES2008

Study ID	ELMOHANDES2008
Bibliographic reference	El-Mohandes AAE, Kiely M, Joseph JG, Subramanian S, Johnson AA, Blake SM, et al. An intervention to improve postpartum outcomes in African-American mothers: a randomized controlled trial. Obstetrics and Gynecology. 2008;112: 611-620.

Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report with blinded interviewers **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 51% of sample had symptoms of depression (Hopkins Symptom Checklist-25 [HSCL-25]:>1.06) **N (number randomised):** 1070 **Mean age (years):** 24.6 **Inclusion criteria:** i) minority statusl ii) age ≥ 18 years; iii) ≤ 28 weeks of pregnant; iv) DC resident; v) English speaking; vi) reporting any of the four designated risks (active smoking [smoking in 6 months prior to pregnancy or since learning they were pregnant]; environomental tobacco smoke [exposure to smokers at home, in the same room, or in a car]; depression and IPV) **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** CBT-informed psychoeducation **Description:** Behavioural counselling for the reported risk factor. The cognitive behavioral therapy intervention for depression was adapted from a group intervention by Miranda and Munoz **Format:** Individual **Group size:** N/A **Sessions:** 5 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Masters trained counselors **Control intervention** **Name:** Treatment as usual **Description:** Usual care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (Hopkins Symptom Checklist [sum/20>0.75]); Drop-out **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Grants no. 3U18HD030445, 3U18HD030447, 5U18HD31206, 3U18HD031919, 5U18HD036194
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear and insufficient detail is reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.17 FIELD2013A

Study ID	FIELD2013A
Bibliographic reference	Field T, Diego M, Delgado J, Medina L. Peer support and interpersonal psychotherapy groups experienced decreased prentatal depression, anxiety and cortisol. Early Human Development. 2013a;89:621-624.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** 100% diagnosed as depressed according to SCID. Baseline CES-D=23.4 (SD 7.2) **N (number randomised):** 48 **Mean age (years):** 24.9 **Inclusion criteria:** i) diagnosis of depression (assessed using SCID); ii) singleton pregnancy; iii) uncomplicated pregnancy with no medical illness; iv) aged <40 years old **Exclusion criteria:** i) drug use (prescribed or illicit)
Interventions	**Experimental intervention** **Name:** IPT **Description:** The interpersonal psychotherapy group sessions were focused on pregnancy experiences and relationship problems. The curriculum for the IPT was based on the Comprehensive Guide to Interpersonal Psychotherapy (Weismann et al., 1977) and the therapist was active and used techniques including exploration, encouragement of affect, clarification, communication analysis, and behaviour change techniques **Format:** Group **Group size:** 8 **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Therapist **Control intervention** **Name:** Peer support group **Description:** The peer support group engaged in discussions on many different topics with active participation from all members, but not from the staff member present who was not a trained therapist and who remained silent throughout **Format:** Group **Group size:** 8 **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Facilitated by staff member (not therapist)
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (CES-D); Anxiety mean scores (STAI); Anger mean scores (STAXI); Maternal stress (salivary cortisol levels); Gestational age; Birthweight **Outcomes not used:** Data not used for Depressed affect subscale of CES-D

Study design	Randomised controlled trial (RCT)
Source of funding	NIH grant (HD056036) and a Senior Research Scientist Award (AT001585) to Tiffany Field and funding from Johnson & Johnson Pediatric Institute to the Touch Research Institute
Limitations	1. High risk of selection bias due to unclear randomisation method and allocation concealment and statistically significant baseline differences with the control group showing a higher SES score/lower income and higher depression (CES-D) mean score 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.18 GAMBLE2005

Study ID	GAMBLE2005
Bibliographic reference	Gamble J, Creedy D, Moyle W, Webster J, McAllister M, Dickson P. Effectiveness of a counseling intervention after a traumatic childbirth: a randomized controlled trial. Birth. 2005;32:11-19.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital and telephone **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% Criterion A of DSM-IV-TR for PTSD (assessed using MINI-PTSD) **N (number randomised):** 103 **Mean age (years):** 28 **Inclusion criteria:** i) over 18 years of age; ii) in the last trimester of pregnancy at time of recruitment; iii) expected to give birth to a live infant at time of recruitment; iv) able to complete questionnaires and interviews in English; v) met Criterion A of DSM-IV-TR for posttraumatic stress disorder (assessed using MINI-PTSD within 72 hours of delivery) **Exclusion criteria:** i) women experiencing stillbirth or neonatal death
Interventions	**Experimental intervention** **Name:** Counselling intervention **Description:** Counselling intervention delivered face-to-face within 72 hours of delivery and by telephone at 4-6 weeks postpartum. Counselling processes incorporated elements of critical stress debriefing and issues pertinent to the childbearing context. Key elements of the intervention included: prompting the woman to tell her own story; listening with encouragement; offering information and answering questions realistically; reviewing labour management; initiating discussion about social support networks; reinforcing positive approaches to coping; and exploring solutions. **Format:** Individual

	Group size: N/A **Sessions:** 2 **Frequency (number of doses per week):** 0.3 **Duration (weeks):** 6 **Provider:** Research midwife **Control intervention** **Name:** Treatment as usual **Description:** The control group received standard postnatal care. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** PTSD diagnosis (MINI); PTSD mean scores (MINI?); Depression symptomatology (EPDS>12); Anxiety symptomatology (DASS-Anxiety>9); Stress symptomatology (DASS-Stress>19); Self-blame mean score **Outcomes not used:** Data not extracted for 4-6 week assessment as mid-treatment. Data not extracted for DASS-Depression as EPDS more widely used scale. Data not extacted for Confidence about future pregnancy
Study design	Randomised controlled trial (RCT)
Source of funding	Queensland Nursing Council and a scholarship from the Faculty of Nursing & Health, Griffith University, Meadowbrook, Queensland, Australia
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.19 GAO2010/2012

Study ID	GAO2010/2012
Bibliographic reference	Gao L-L, Chan SW-C, Li X, Chen S, Hao Y. Evaluation of an interpersonal-psychotherapy-oriented childbirth education programme for Chinese first-time childbearing women: a randomised controlled trial. International Journal of Nursing Studies. 2010;47:1208-1216. Gao L-L, Chan SW-C, Sun K. Effects of an interpersonal-psychotherapy-oriented childbirth education programme for Chinese first-time childbearing women at 3-month follow up: randomised controlled trial. International Journal of Nursing Studies. 2012;49:274-281.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (primary) **Country:** China
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Baseline EPDS = 7.99 (3.1) **N (number randomised):** 194

	Mean age (years): 28.4 **Inclusion criteria:** i) women with normal pregnancies with null parity; ii) aged <=35 years old; iii) married and living with their husbands; iv) with a gestational age over 28 weeks; v) no personal or family histories that included psychiatric disorders or pregnancy complications **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Interpersonal-psychotherapy (IPT)-oriented childbirth psychoeducation programme **Description:** The group received routine antenatal education and the Interpersonal-psychotherapy (IPT)-oriented childbirth psychoeducation programme. The programme was based on the principles of IPT, on previous qualitative and quantitative studies on the predictors of postnatal depression amongst Chinese women. The intervention targeted the specific concerns and interpersonal problem areas (role transitions and interpersonal conflicts) experienced by women during the postpartum period. Specific IPT techniques, such as information giving, clarification, communication analysis, role-playing and brainstorming, were applied throughout the programme. Written material was also provided to the participants in each session. The intervention consisted of two antenatal group sessions and a postnatal telephone follow-up. The aims of the follow-up were to reinforce skills learnt in the group sessions and to deal with any current or anticipated mood changes or interpersonal issues during the postpartum period **Format:** Individual and group **Group size:** Up to 10 **Sessions:** 3 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Midwife **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Routine antenatal education focused on the delivery process and child care **Format:** Group **Group size:** Not reported **Sessions:** 2 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Midwife
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS=>13); Depression mean scores (EPDS); General mental health (GHQ); Social support (PSSS); Maternal competence (POSC-E) **Outcomes not used:** Data was not extracted for Satisfaction with Interpersonal Relationships Scale (SWIRS)
Study design	Randomised controlled trial (RCT)
Source of funding	None
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.20 GROTE2009

Study ID	GROTE2009
Bibliographic reference	Grote NK, Swartz HA, Geibel SL, Zuckoff A, Houck PR, Frank E. A randomized controlled trial of culturally relevant, brief interpersonal psychotherapy for perinatal depression. Psychiatric Services. 2009;60:313-321.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or unclear blinding of outcome assessment **Setting:** Clinic (secondary) **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 100% EPDS>12. Baseline mean EPDS = 18.5 (SD 2.4). Baseline mean BDI=25.1 (SD 7.1). Baseline mean BAI=15.4 (SD 7.6). SCID diagnosis: 85% major depression; 13% dysthymia; 13% comborbid major depression and dysthymia; 6% minor depression; 23% panic disorder; 23% PTSD; 17% social phobia; 51% = >1 anxiety disorder **N (number randomised):** 53 **Mean age (years):** 24.5 **Inclusion criteria:** i) 18 years or older; ii) 10-32 weeks gestation; iii) EDPDS score>12; iv) English-speaking; v) access to a telephone; vi) living in the Pittsburgh region **Exclusion criteria:** i) substance abuse or dependence within the preceding 6 months; ii) actively suicidal; iii) bipolar disorder, a psychotic disorder, or an organic mental disorder; iv) an unstable medical condition that could produce symptoms confounding accurate assessment of mood symptoms (for example, untreated thyroid disease); v) severe intimate partner violence; vi) current receipt of another form of depression treatment (that is, psychotherapy or pharmacotherapy)
Interventions	**Experimental intervention** **Name:** Enhanced Brief Interpersonal Psychotherapy (IPT-B) **Description:** Enhanced IPT-B is a multicomponent model of care consisting of an engagement session, acute IPT-B, and maintenance IPT. It is also augmented with culturally relevant modifications. The engagement session is based on principles of motivational interviewing and ethnographic interviewing and is designed to promote engagement by building trust and addressing the practical, psychological, and cultural barriers to care experienced by individuals who are socioeconomically disadvantaged. More specifically, during engagement, the interviewer elicits each participant's unique barriers to care and engages in collaborative problem solving to ameliorate each barrier. The acute sessions (IPT-B), similar to IPT, were designed to treat depression by helping patients resolve one of four interpersonal problem areas (that is, role transition, role dispute, grief, and interpersonal deficits) related to the onset or maintenance of a depressive episode. Maintenance sessions encouraged participants to be mindful of early somatic, affective, or cognitive symptoms related to prior depressive episodes and to practice skills learned in IPT-B to prevent relapse **Format:** Individual **Group size:** N/A **Sessions:** 15-21

	Frequency (number of doses per week): Variable (single engagement session, followed by eight acute biweekly IPT-B sessions before the birth and monthly maintenance IPT up to six months postpartum) **Duration (weeks):** 44 **Provider:** Therapist (one doctoral-level clinician and one master's level clinician) **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Participants assigned to enhanced usual care were informed of their diagnoses, given written educational materials about depression, and were strongly encouraged to seek treatment at the behavioral health center located in the obstetrics and gynecology clinic where they were receiving prenatal services (or at the neighborhood mental health center, if they preferred). Enhanced usual care participants were provided the same advantages as the IPT-B group to help them overcome practical barriers—easy access to depression treatment in the obstetrics and gynecology clinic, familiarity with the setting, decreased stigma, childcare, and free bus passes. In addition, participants in the enhanced usual care group received more monitoring of their depression severity and diagnostic status than they typically received in the clinic, in as much as research staff contacted them every three weeks to assess their mood and to encourage them to enter treatment, as indicated. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 44 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (SCID); Depression symptomatology (50% improvement on EPDS); Depression mean scores (EPDS); Anxiety mean scores (BAI); Life functioning (SAS) **Outcomes not used:** Data not extacted for time 2 as mid-treatment. BDI mean scores not extracted as EPDS more widely reported
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH Grant K23-MH67595, a grant from the Staunton Farm Foundation, and grant MO1-RR000056 from the General Clinical Research Centers, National Center for Research Resources
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Unclear risk of detection bias for depression diagnosis (SCID) as blinding of outcome assessor is unclear 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.21 GUARDINO2014

Study ID	GUARDINO2014
Bibliographic reference	Guardino CM, Schetter CD, Bower JE, Lu MC, Smalley SL. Randomised controlled pilot trial of mindfulness training for stress reduction during pregnancy. Psychology and Health. 2014;29:334-349.

Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (secondary) **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** Baseline STAI-State mean=45 (SD 5.5) **N (number randomised):** 47 **Mean age (years):** 33.1 **Inclusion criteria:** i) pregnant women at 10-25 weeks gestation with a singleton pregnancy; ii) could speak and read English fluently; iii) were over the age of 18; iv) were willing and able to attend the six-week mindfulness course; v) were willing and able to provide informed consent; vi) were experiencing elevated levels of perceived stress (PSS>34) or pregnancy-specific anxiety (PSA>11) **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Mindful Awareness Practices (MAPS) classes **Description:** Particpants were enrolled in the UCLA Semel Institute's Mindful Awareness Research Center's (MARC) ongoing Mindful Awareness Practice (MAPS) classes that included members of the UCLA community and general public who were not pregnant or enrolled in the study. Each class series followed a manualized curriculum and participants were trained in the practice of mindfulness meditation and its applications to daily life through participation in instructor-led group meditations, lectures about mindfulness practices and group discussions. Participants were also given a CD with recordings of instructor-guided meditations to use at home, and provided with homework assignments each week (daily meditations for 5-17 minutes) **Format:** Group **Group size:** Not reported **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Trained instructor **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Participants in the control group were mailed a copy of the book 'You and Your Baby: Pregnancy' (Riley, 2006) which covers each trimester of pregnancy in a week-by-week format and slo includes information about labour and delivery, feeding, and postpartum and baby care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 6 **Provider:** Self
Outcomes	**Outcomes used:** Drop-out; Anxiety mean score (STAI); Parental stress (PSS) **Outcomes not used:** Data not extracted for time 2 as <9 week follow-up and Mindfulness (FFMQ), Pregnancy-Specific Anxiety (PSA) and PRA not extracted
Study design	Randomised controlled trial (RCT)

Source of funding	UCLA Academic Senate and the UCLA Center for the Study of Women. Christine M. Guardino was supported by National Institute of Mental Health Training Grant #15750
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.22 HAGAN2004

Study ID	HAGAN2004
Bibliographic reference	Hagan R, Evans SF, Pope S. Preventing postnatal depression in mothers of very preterm infants: a randomised controlled trial. BJOG. 2004;111:641-647.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Not reported **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Median EPDS at baseline: 8 **N (number randomised):** 199 **Mean age (years):** Median: 29 **Inclusion criteria:** i) admission of very preterm or very low birthweight infant; ii) English speaking; iii) lived in or near Perth **Exclusion criteria:** i) history of psychotic disorder; ii) current treatment for unipolar or bipolar depression; iii) triplet pregnancy; iv) significant substance abuse; v) infant unlikely to survive first week; vi) infant requiring early transfer to Children's Hospital for surgery; vii) assessment measures culturally inappropriate; viii) maternal age <17 years
Interventions	**Experimental intervention** **Name:** Cognitive behaviour model group session **Description:** Brief individual pregnancy debriefing discussion related to their pregnancy experience.The research midwife then facilitated six weekly group sessions. A cognitive –behaviour therapy model provided the basis for these sessions but they also included an educational component and advice on how to cope with the practical problems of the first few weeks and months. The sessions dealt with the following issues: adjustment to parenthood with a preterm infant; explaining postnatal depression; coping with emotional and physical changes; identifying and altering negative patterns of thinking; daily and weekly activity planning and developing self-nurturing strategies; communication issues in relationships and setting short term and long term goals. **Format:** Group **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Midwife **Control intervention**

	Name: Treatment as usual **Description:** Women assigned to the control group received the standard care for mothers of preterm infants in King Edward Memorial Hospital for Women. This included social work contact for all mothers, regular biweekly parent education group sessions and a developmental physiotherapy playgroup during the first year **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (Schedule for Affective Disorders and Schizophrenia [SADS]); Anxiety diagnosis (SADS); Adjustment disorders diagnosis (SADS); Any psychopathology (SADS); Drop-out **Outcomes not used:** Data could not be extracted for continuous measures of depression (EPDS, BDI, GHQ) as means and sds not reported (median and interquartile ranges reported)
Study design	Randomised controlled trial (RCT)
Source of funding	Western Australian Health Promotion Foundation (Healthway) and the Women and Infants Research Foundation, Perth
Limitations	1. High risk of selection bias due to statistically significant baseline group difference in previous preterm infant (15% for control group and 6% for intervention group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data could not be extracted for continuous measures of depression (EPDS, BDI, GHQ) as means and sds not reported (median and interquartile ranges reported)
Notes	None

1.11.23 HAYDEN2012

Study ID	HAYDEN2012
Bibliographic reference	Hayden T, Perantie DC, Nix BD, Barnes LD, Mostello DJ, Holcomb WL, et al. Treating prepartum depression to improve infant developmental outcomes: a study of diabetes in pregnancy. Journal of Clinical Psychology in Medical Settings. 2012;19:285-292.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** Mean BDI at baseline: 25.6 (9.1) **N (number randomised):** Unclear (completer analysis reported: N=34) **Mean age (years):** 31 **Inclusion criteria:** i) pregnant women who met DSM-IV criteria for major

	depressive disorder; ii) aged 15–44; 3) preexisting diabetes (type 1 or type 2 or gestational) requiring insulin during pregnancy preexisting diabetes (type 1 or type 2 or gestational) requiring insulin during pregnancy **Exclusion criteria:** i) multiple gestation; ii) illiteracy in English; iii) illicit drug use; iv) hemolytic anemia; v) current suicidal/homicidal ideation; vi) history of psychotic or bipolar disorder
Interventions	**Experimental intervention** **Name:** CBT **Description:** CBT focuses on identifying and eliminating maladaptive thoughts evident in MDD. **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10 **Provider:** Licensed clinical social worker **Control intervention** **Name:** Supportive counselling **Description:** Supportive counselling consists of nondirective and nonspecific support in the form of empathic listening and unconditional acceptance. **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10 **Provider:** Licensed clinical social worker
Outcomes	**Outcomes used:** Depression mean score (BDI); Infant cognitive development (Bayley Scales of Infant Development-Mental Development Index); Infant physical development (Bayley Scales of Infant Development-Psychomotor Development Index) **Outcomes not used:** Data not reported for Behavior Rating Scale (BRS). Data not extracted for Fagan Test of Infant Intelligance (Fagan) as Bayley Scales of Infant Development also reported and these are more widely used measure of infant cognitive development
Study design	Randomised controlled trial (RCT)
Source of funding	NIH grants K24DK059364 and R01DK036452
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data not reported for Behavior Rating Scale (BRS) 4. Risk of attrition bias is unclear as N randomized to groups not clear and only completer data reported
Notes	None

1.11.24 HISCOCK2002

Study ID	HISCOCK2002

Bibliographic reference	Hiscock H, Wake M. Randomised controlled trial of behavioural infant sleep intervention to improve infant sleep and maternal mood. British Medical Journal. 2002;324:1062-1065.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (primary) **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Data were only extracted for the 'depressed' subgroup (EPDS=>10) (N=66) **N (number randomised):** 66 (data only extracted for 'depressed' subgroup) **Mean age (years):** Not reported for subgroup **Inclusion criteria:** i) mothers reporting a problem with their infant's sleep and at least one of the following over the preceding two weeks: waking on more than five nights a week; waking more than three times a night; taking more than 30 minutes to fall asleep or requiring parental presence to fall asleep; ii) EPDS score=>10 (for subgroup data extracted) **Exclusion criteria:** i) insufficient English to complete questionnaires; ii) current treatment for either infant sleep problems or postnatal depression; iii) thoughts of self-harm; iv) infants with a major medical or developmental problem
Interventions	**Experimental intervention** **Name:** Controlled crying **Description:** Mothers in the intervention group attended three private consultations, held fortnightly at their local maternal and child health centre. Sleep management plans were tailored towards individual families. As well as discussing normal sleep cycles, parents were taught that settling after night waking is a learned behaviour that can be modified, infants need to be taught to fall asleep independently, factors reinforcing the sleep problem can be eliminated with appropriate behavioural interventions, an infant's cry may be for more than one reason, and a bedtime routine and consistent daytime naps are desirable. The main intervention was controlled crying, whereby parents responded to their infant's cry at increasing time intervals, allowing the infant to fall asleep by itself. A few parents chose "camping out," whereby they sat with their infant until the infant fell asleep and gradually removed their presence over a period of three weeks. Overnight feeding that contributed to night waking was managed by reducing over seven to 10 days the volume of milk given or time taken to feed. When a dummy was causing problems (needing a parent to find and replace it), parents removed it or attached it to the infant's clothing overnight. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 0.5 **Duration (weeks):** 6 **Provider:** Not reported **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Mothers in the control group were mailed a single sheet describing normal sleep patterns in infants aged 6 to 12 months based on

	Australian normative data. This sheet did not include advice on how to manage infant sleep problems. **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 6 **Provider:** Self
Outcomes	**Outcomes used:** Depression mean change scores (EPDS); Infant sleep problems **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Research Institute, Royal Children's Hospital, Melbourne, and a Public Health Postgraduate National Health and Medical Research Council Scholarship
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method is unclear as paper reports ITT but method unclear and Ns vary across outcome measures so assume available case. It was not possible to compute ITT (WCS) as number randomised and dropout unclear 4. Risk of selective reporting bias is unclear/unknown 5. Risk of attrition bias is unclear as N randomized to groups not clear for subgroup analysis and only completer data reported
Notes	Data only extracted for 'depressed' subgroup

1.11.25 HISCOCK2007/HISCOCK2008

Study ID	HISCOCK2007/HISCOCK2008
Bibliographic reference	Hiscock H, Bayer J, Gold L, Hampton A, Ukoumunne OC, Wake M. Improving infant sleep and maternal mental health: a cluster randomised trial. Archives of Disease in Childhood. 2007;92:952-958. Hiscock H, Bayer JK, Hampton A, Ukomunne OC, Wake M. Long-term mother and child mental health effects of a population-based infant sleep intervention: cluster-randomized, controlled trial. Pediatrics. 2008;122:e621-627.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** Subgroup data (HISCOCK2007): 100% EPDS>9. Whole sample data (HISCOCK2008): Baseline EPDS mean=8.4 (SD 3.9) **N (number randomised):** Subgroup data (HISCOCK2007): Unclear. Whole sample data (HISCOCK2008): 328 **Mean age (years):** Not reported

	Inclusion criteria: i) mothers of 4-month-old infants attending maternal and child health visit; ii) Mothers reporting an infant sleep problem in the concurrent 7-month questionnaire; iii) For subgroup data (HISCOCK2007): EPDS>9 **Exclusion criteria:** i) infants born before 32 weeks' gestation; ii) mothers with insufficient English to complete questionnaires
Interventions	**Experimental intervention** **Name:** Controlled crying or camping out **Description:** At the first consultation nurses elicited the nature of the sleep problem, identified solutions, and wrote an individualised sleep management plan with the mother. Two handouts discussed normal sleep patterns at 6–12 months and sleep associations and their causal role in sleep problems. Handouts on managing problem overnight feeding and dummies were also available. Mothers were offered the choice of two behavioural interventions: i) ''controlled crying' or ii) ''camping out''. Mothers maintained daily sleep diaries until the follow-up appointment 2 weeks later, to facilitate recognition of sleep patterns and improvements and to help set further goals. **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** Not reported **Duration (weeks):** 2 **Provider:** Maternal and child health nurse **Control intervention** **Name:** Treatment as usual **Description:** No infant sleep intervention **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 2 **Provider:** Not reported
Outcomes	**Outcomes used:** Subgroup data (symptoms/HISCOCK2007): Infant sleep problems (maternal report); Depression mean scores (EPDS). Whole sample data (sub-threshold/HISCOCOK2008): Depression symptomatology (EPDS>9); Depresison mean scores (EPDS); Infant socio-emotional development (CBCL/1.5-5) **Outcomes not used:** Data could not be extracted for the whole sample in HISCOCK2007 as Ns not reported in table, and sub-group data not reported for maternal sleep quality and quantity, SF12- physical and mental health, or Global Infant Temperament scale. Data not extracted for Parent Behaviour Checklist
Study design	Randomised controlled trial (RCT)
Source of funding	National Health and Medical Research Council Project, grant number 237120 and The Pratt Foundation
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method is unclear as paper reports ITT but method unclear and Ns vary across outcome measures

	so assume available case. It was not possible to compute ITT (WCS) as number randomised and dropout unclear for subgroup analysis 4. Risk of selective reporting bias is unclear/unknown as although paper reports that protocol is registered (ISRCTN65502576) it cannot be found 5. Risk of attrition bias is unclear as N randomized to groups not clear for subgroup analysis and only completer data reported
Notes	HISCOCK2007: Data only extracted for EPDS>9 and data cannot be extracted for whole sample as Ns not reported in table. HISCOCK2008: Data only reported for whole sample which is sub-threshold based on mean baseline EPDS

1.11.26 HOLDEN1989

Study ID	HOLDEN1989
Bibliographic reference	Holden JM, Sagovsky R, Cox JL. Counselling in a general practice setting: controlled study of health visitor intervention in treatment of postnatal depression. British Medical Journal. 1989;298:223-226.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% Depression by Goldberg's Standardised Psychiatric Interview and research diagnostic criteria **N (number randomised):** 55 **Mean age (years):** 26.2 **Inclusion criteria:** i) mothers who scored above the threshold of 12/13 on the EPDS 6 weeks after delivery; ii) after psychiatric interview at 12 weeks after delivery were found to be depressed according to research diagnostic criteria **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Counselling **Description:** The health visitors who had been given a short training in counselling for postnatal depression were asked to visit women in the treatment group at a prearranged time for eight successive weeks. At least half an hour was to be spent counselling, infant care being discussed separately. The teaching programme was based on Rogerian or non-directive counselling methods; individuals talking about feelings to an empathic and non-judgmental professional in order to take a more positive view of themselves and their lives. **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** 1 **Duration (weeks):** 13 **Provider:** Health visitor **Control intervention**

	Name: Treatment as usual **Description:** Standard care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 13 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (Goldberg's standardised psychiatric interview) **Outcomes not used:** Data cannot be extracted for EPDS mean scores as median scores only reported. Data also cannot be extracted for drop-out as attrition is not split by group
Study design	Randomised controlled trial (RCT)
Source of funding	Scottish Home and Health Department
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective rpeorting bias as data cannot be extracted for EPDS as a continuous outcome measure as median rather than mean scores reported. Data also cannot be extracted for drop-out as attrition is not split by group 4. Risk of attrition bias is unclear as drop-out is not split by group
Notes	None

1.11.27 HONEY2002

Study ID	HONEY2002
Bibliographic reference	Honey KL, Bennett P, Morgan M. A brief psycho-educational group intervention for postnatal depression. British Journal of Clinical Psychology. 2002;41:405-409.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% EPDS>12. Baseline EPDS = 19.15 (4.17) **N (number randomised):** 45 **Mean age (years):** 27.9 **Inclusion criteria:** i) screened positively for probable PND (EPDS>12); ii) were not exhibiting psychotic symptoms; iii) their most recent child was below 12 months of age **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Brief psychoeducation group (PEG) **Description:** This intervention comprised three components: (1) educational,

	providing information on PND, strategies for coping with difficult child-care situations and eliciting social support; (2) use of cognitive–behavioural techniques to tackle women's erroneous cognitions about motherhood and provide strategies for coping with anxiety; and (3) teaching the use of relaxation. While the intervention was not manualized, group sessions were structured according to a pre-defined programme **Format:** Group **Group size:** 4-6 **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Health visitor **Control intervention** **Name:** Treatment as usual **Description:** Routine primary care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression mean scores (EPDS); Drop-out **Outcomes not used:** Data could not be extracted for Duke-UNC Social Support Questionnaire; Dyadic (Marital) Adjustment Scale; Ways of Coping Checklist Revised
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the Wales Office of Research and Development for Health and Social Care
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear and insufficient detail is reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data cannot be extracted for Duke-UNC Social Support Questionnaire; Dyadic (Marital) Adjustment Scale; Ways of Coping Checklist Revised
Notes	None

1.11.28 HOROWITZ2001

Study ID	HOROWITZ2001
Bibliographic reference	Horowitz JA, Bell M, Trybulski J, Munro BH, Moser D, Hartz SA, et al. Promoting responsiveness between mothers with depressive symptoms and their infants. Journal of Nursing Scholarship. 2001;33:323-329.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Home

	Country: US
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% EPDS = > 10 **N (number randomised):** 122 **Mean age (years):** 31 **Inclusion criteria:** i) English-speaking women; ii) infants discharged with a normal newborn exam; iii) EPDS score = >10 **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Maternal-infant Interaction Coaching + Assessment **Description:** Interaction coaching for at-risk parents and their infants (ICAP) is an intervention strategy designed to strengthen the early dyadic relationship. ICAP began with a 5-minute observation of mother-infant face-to-face interaction. Six key elements comprised the intervention: (a) teaching the mother to identify the infant's behavioral cues and to tailor responses to match the infant's preferences, (b) guiding the mother to position the infant in her line of vision, (c) demonstrating ways to modulate the use of pauses, imitation, sequences, and combinations of her facial expression, voice, and touch, (d) encouraging practice of suggestions and trial-and-error learning, (e) reinforcing sensitive responsiveness whenever it occurred, and (f) praising success. These elements were repeated and varied, depending on the unique needs of each mother-infant pair. Each interactive coaching session took approximately 15 minutes. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 0.17 **Duration (weeks):** 18 **Provider:** Advanced practice nurse **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Maternal-infant interaction assessment by video but no coaching. Received standard postpartum primary care and also could receive additional psychiatric treatment for depression as needed. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 0.17 **Duration (weeks):** 18 **Provider:** Advanced practice nurse
Outcomes	**Outcomes used:** Mean depresison scores (BDI-II); Positive mother-infant interactions (DMC) **Outcomes not used:** Data cannot be extracted for drop-out as group allocation unclear. Data not extracted for Time 1 and 2 as mid-treatment
Study design	Randomised controlled trial (RCT)
Source of funding	Research Grant No. 12-FY98-0014 from the March of Dimes Birth Defects Foundation and a Research Incentive Grant from Boston College
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel

	3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.29 KAAYA2013

Study ID	KAAYA2013
Bibliographic reference	Kaaya SF, Blander J, Antelman G, Cyprian F, Emmons KM, Matsumoto K, et al. Randomized controlled trial evaluating the effect of an interactive group counseling intervention for HIV-positive women on prenatal depression and disclosure of HIV status. AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV. 2013;25:854-862.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Tanzania
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 73% HSCL-25>1.06 **N (number randomised):** 331 **Mean age (years):** 26 **Inclusion criteria:** i) gestational age < 27 weeks; ii) = >18 years of age; iii) intended to deliver in Dar es Salaam and stay in the city for at least one year after delivery; iv) HIV-positive **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Group counselling intervention for HIV-positive women **Description:** The intervention consisted of a structured, closed group counseling intervention that used components of a problem-solving therapy approach. Topics addressed during the intervention included: challenges in being HIV-positive; HIV transmission prevention challenges; the impact of HIV on health; accessing health care and social services; ways to reduce mother-to-child transmission; continued discussions on disclosure to partners, family, and friends. Throughout the intervention the group format was intended to provide psychosocial support in order to facilitate sharing of risk and anxiety reduction strategies **Format:** Group **Group size:** 6-8 **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Not reported **Control intervention** **Name:** Treatment as usual **Description:** Standard care typically consisted of information on how to access PMTCT (Preventing Mother-to-Child Transmission of HIV) services, but typically did not include social support group counselling. **Format:** Individual

	Group size: N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 6 **Provider:** N/A
Outcomes	**Outcomes used:** Depression symptomatology (HSCL-25>1.06); Drop-out **Outcomes not used:** Data not extracted for HIV status disclosure or for EoC (as very specific to HIV-support group)
Study design	Randomised controlled trial (RCT)
Source of funding	Supplemental grant from the National Institute of Child Health and Human Development (R0132257)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.30 KERSTING2011

Study ID	KERSTING2011
Bibliographic reference	Kersting A, Kroker K, Schlicht S, Baust K, Wagner B. Efficacy of cognitive behavioral internet-based therapy in parents after the loss of a child during pregnancy: pilot data from a randomized controlled trial. Archives of Womens Mental Health. 2011;14:465-477.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Internet **Country:** Germany
Participants	**Timing:** Post-miscarriage, termination due to fetal abnormality, or stillbirth **Baseline symptoms:** Baseline IES mean=33.7 (SD 10.1) **N (number randomised):** 83 **Mean age (years):** 34.3 **Inclusion criteria:** i) self-referring women who had lost a baby due to miscarriage, termination for fetal abnormality, or stillbirth; ii) living in a German-speaking country; iii) speaking German as a first language; iv) had access to the internet; v) gave informed consent **Exclusion criteria:** i) women with severely depressed mood and suicidal temdencies (BSI); ii) dissociative tendencies (Somatoform Dissociation Questionnaire); iii) risk of psychosis (SDPD); iv) substance abuse and dependence; v) pregnancy at treatment allocation; vi) psychotherapy at treatment allocation; vii) age<18 years
Interventions	**Experimental intervention** **Name:** Internet-based CBT for complicated grief **Description:** The internet-based CBT consisted of 3 phases: self-confrontation, where participants wrote 4 assignments describing the traumatic loss and its circumstances; cognitive restructuring, where participants wrote a further 4 assignments, framed as a supportive letter to a hypothetical friend with the aim of providing new perspectives on the loss; and the final phase of social

	sharing, which involved a further 2 assignments focused on a symbolic farewell letter to themselves/person connected with the loss/loved one. Twice in each phase, the therapist provided (within 1 working day) individual written feedback along with instructions on the next writing assignment **Format:** Individual **Group size:** N/A **Sessions:** 0 contact with professionals (10 written assignments) **Frequency (number of doses per week):** 2 **Duration (weeks):** 5 **Provider:** Therapist **Control intervention** **Name:** Waitlist **Description:** Waitlist **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 5 **Provider:** N/A
Outcomes	**Outcomes used:** PTSD symptomatology (reliable change index); PTSD mean scores (IES); Depression symptomatology (reliable change index); Depression mean scores (BSI); Anxiety symptomatology (reliable change index); Anxiety mean scores (BSI); General mental health symptomatology (reliable change index); General mental health mean scores (BSI); Drop-out **Outcomes not used:** Data was not extracted for Grief (Inventory of Complicated Grief [ICG]) or for somatization sub-scale of the BSI
Study design	Randomised controlled trial (RCT)
Source of funding	This project was fully funded by the German Federal Ministry for Family Affairs, Senior Citizens, Women, and Youth
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.31 KOZINSZKY2012

Study ID	KOZINSZKY2012
Bibliographic reference	Kozinszky Z, Dudas RB, Devosa I, Csatordai S, Tóth É, Szabó D, et al. Can a brief antepartum preventive group intervention help reduce postpartum depressive symptomatology? Psychotherapy and Psychosomatics. 2012;81:98-107.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Not reported **Country:** Hungary
Participants	**Timing:** Antenatal **Baseline symptoms:** Depressed subgroup: Leverton Questionnaire (LQ; Elliott

	et al., 2000)=>12 **N (number randomised):** Total sample: 1762. Depressed subgroup (Treatment-symptoms): 324. Non-depressed subgroup (Prevention-No risk factors): 1438 **Mean age (years):** 27.3 **Inclusion criteria:** i) pregnant women living in the area **Exclusion criteria:** i) other reasons for depression (for example depression related to mourning or organic causes, or depression due to chronic physical illness not related to the pregnancy or delivery); ii) any neurological or psychiatric problems (such as epilepsy); iii) illiteracy; iv) stillbirth or perinatal death
Interventions	**Experimental intervention** **Name:** Brief preventive group intervention for postpartum depression **Description:** Psychologically-informed psychoeducation group sessions grounded in principles of group therapy, interpersonal psychotherapy, and cognitive-behavioral therapy. Intervention content consisted of: patient education (including risk factors, prevalence, symptoms and pharmacological and psychological treatment of postnatal depression); postnatal depression screening and coping skills (including the mother role, developing coping mechanisms, stress reduction techniques, recognising link between negative thoughts and mood, and problem-solving techniques); recognizing distress and seeking help (including thoughts/feelings that might be red flags to prompt help-seeking, reducing self-criticism, and communciation skills); recapitulation and relaxation (including summarizing, peer feedback, and practising relaxation techniques). **Format:** Group **Group size:** Up to 15 **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 4 **Provider:** Psychiatrists and health visitors with a special interest and training in psychiatry **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Routine education on pregnancy, childbirth, and baby care, (more or less identical to treatment as usual) although in more rural areas this type of education would be more likely to be given in an individual rather than group format **Format:** Group **Group size:** Not reported **Sessions:** 4 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (Leverton Questionnaire [LQ; Elliott et al., 2000]=>12) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel

	2. Risk of selective reporting bias is unclear/unknown
Notes	Outomes for both i) Treatment-symptoms; ii) Prevention- no risk factors

1.11.32 LE2011

Study ID	LE2011
Bibliographic reference	Le H-N, Perry DF, Stuart EA. Randomized controlled trial of a preventive intervention for perinatal depression in high-risk latinas. Journal of Consulting and Clinical Psychology. 2011;79:135-141.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Inclusion criteria: 16 or higher on the Center for Epidemiological Studies Depression Scale and/or with a self-reported personal or family history of depression. Approximately 25% had BDI >20 at baseline. Baseline BDI-II mean=15.3 (SD 6.5) **N (number randomised):** 217 **Mean age (years):** 25.4 **Inclusion criteria:** i) age 18 –35 years; ii) 24 weeks gestation; iii) at high risk for depression, defined as CES-D>16 and/or with a self-reported personal or family history of depression **Exclusion criteria:** i) smoking, alcohol, or illicit substance abuse; ii) current diagnosis of major depressive disorder, substance abuse, psychosis, a serious medical condition, and/or other significant psychosocial problems.
Interventions	**Experimental intervention** **Name:** CBT-informed psychoeducation **Description:** Teaching women mood regulation skills to prevent perinatal depression (Le & Mun˜oz, 2004). The Mothers and Babies intervention was based on previous work by Mun˜oz et al. (2001), including detailed instructor's and participants' manuals. Specific cultural adaptations were made in the structure and content of the course based upon data gathered from focus groups **Format:** Group **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Allied Health **Control intervention** **Name:** Treatment as usual **Description:** Usual care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8

	Provider: Not reported
Outcomes	**Outcomes used:** Drop-out; Depression diagnosis (MMS) **Outcomes not used:** Data cannot be exracted for depression mean scores (BDI-II) or depression symptomatology (BDI=>20). Data not extracted for 6-week follow-up as <9 weeks follow-up
Study design	Randomised controlled trial (RCT)
Source of funding	Grant R40 MC 02497 from the Maternal and Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration, Department of Health and Human Services (Huynh-Nhu Le, principal investigator)
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data cannot be exracted for depression mean scores (BDI-II) or depression symptomatology (BDI=>20)
Notes	None

1.11.33 LETOURNEAU2011

Study ID	LETOURNEAU2011
Bibliographic reference	Letourneau N, Stewart M, Dennis C-L, Hegadoren K, Duffett-Leger L, Watson B. Effect of home-based peer support on maternal-infant interactions among women with postpartum depression: a randomized, controlled trial. International Journal of Mental Health Nursing. 2011;20:345-357.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home and/or telephone **Country:** Canada
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS >12 **N (number randomised):** 60 **Mean age (years):** Not reported **Inclusion criteria:** i) EPDS score> 12; ii) were caring for an infant less than 9 months of age; iii) had a singleton birth; iv)the infant did not have a significant health issue; v) mother spoke and understood English; vi) mother lived within driving distance of the research cities in two Canadian provinces (Alberta and New Brunswick). **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Peer- support and maternal infant interaction intervention **Description:** Peer volunteers (who had recovered from postpartum depression symptoms) were trained to provide four types of support, including informational (for example conveying information about postpartum depression), emotional (for example listening), affirmational (for example support aimed at promoting self-esteem and self-confidence), and practical

	(for example child care). The peer volunteers were also trained to teach mothers specific information about optimal mother-infant interactions from Keys to Caregiving programme (NCAST 1999). Beginning in week 3, peer volunteers provided mothers with a video and pamphlets about: (i) infants' states; (ii) infants' behaviour; (iii) infants' cues; (iv) how to modulate states; and (v) interacting during feeding. Mentors were trained to role model and reinforce positive parenting behaviours **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** Not reported **Duration (weeks):** 12 **Provider:** Peer volunteers (mothers who had history of postnatal depression symptoms) **Control intervention** **Name:** Waitlist **Description:** Participants assigned to the control condition received 2 weeks of peer support after a 12-week waiting period. During the 12-week waiting period, all data were collected. Mothers in both groups received standard postpartum care provided by their family physician, public health nurses, and other supports available in their communities. In Canada's publically-funded healthcare system, reproductive services vary across provinces; in Alberta, a variety of community services were available to help mothers with postpartum depression, such as support groups and crisis counselling, while in New Brunswick, mothers relied largely on their family doctors and public health nurses, as other supports were difficult to access in a timely manner **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 12 **Provider:** N/A
Outcomes	**Outcomes used:** Depression mean score (EPDS); Mother-infant feeding interaction (NCAST); Mother-infant teaching interaction (NCAST); Infant cognitive development (Bayley MDI); Infant 'difficult' temperament (ICQ); Social support (SPS); Maternal stress (cortisol); Infant stress (cortisol) **Outcomes not used:** Data not extracted for 6-week follow-up as this was mid-treatment
Study design	Randomised controlled trial (RCT)
Source of funding	March of Dimes, CIHR Peter Lougheed Foundation, and the Harrison McCain Foundation
Limitations	1. Risk of selection bias is unclear/unknown as the randomisation method is unclear 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.34 LEUNG2012

Study ID	LEUNG2012
Bibliographic reference	Leung SS, Lam TH. Group antenatal intervention to reduce perinatal stress and depressive symptoms related to intergenerational conflicts: a randomized controlled trial. International Journal of Nursing Studies. 2012;49:1391-1402.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** China
Participants	**Timing:** Antenatal **Baseline symptoms:** 35% EPDS>12. Baseline EPDS=7.96 (SD 3.7) **N (number randomised):** 156 **Mean age (years):** 31.2 **Inclusion criteria:** i) pregnant at 14–32 weeks' gestation; ii) aged 18 years old or above; iii) Hong Kong residents; iv) able to communicate in spoken and written Chinese; v) having at least a parent-in-law living in Hong Kong. **Exclusion criteria:** i) those who will not stay in Hong Kong after childbirth or the newborn will be taken care by someone outside Hong Kong; ii) those diagnosed with mental illness or have past history of mental illness or requiring medication for mental illness.
Interventions	**Experimental intervention** **Name:** Interpersonal psychotherapy oriented group intervention **Description:** The intervention targeted interpersonal issues identified in qualitative studies of Chinese women in the perinatal period, including intergenerational conflicts and role transitions. Intervention included (1) the use of a short video clip to stimulate discussion; (2) participant identification of errors and development of alternative strategies; (3) role-play; and (4) weekly homework for practice. Each of the four sessions had a distinct simple focus to ensure understanding and a clear take-home message. At the end of each session, participants were given a homework assignment to practice the skills or behaviors discussed in the session. **Format:** Group **Group size:** Not reported **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 4 **Provider:** First author (Leung) and an interventionist with a psychology background **Control intervention** **Name:** Treatment as usual **Description:** Routine antenatal care from the MCHC, which included a physical examination and brief individual interview with a midwife during which participants could raise any health or pregnancy related questions or concerns **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4

	Provider: Midwife
Outcomes	**Outcomes used:** Depression mean scores (EPDS); Parental stress (PSS); Happiness (Subjective Happiness Scale); Drop-out **Outcomes not used:** Relationship Efficacy Measure; Cooperation; Perceived Health
Study design	Randomised controlled trial (RCT)
Source of funding	Hong Kong Jockey Club Charities Trust
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel
Notes	Protocol registered: HKCTR-1458

1.11.35 MILGROM2005B

Study ID	MILGROM2005B
Bibliographic reference	Milgrom J, Negri LM, Gemmill AW, McNeil M, Martin PR. A randomized controlled trial of psychological interventions for postnatal depression. British Journal of Clinical Psychology. 2005b;44:529-542.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report and blinded outcome assessment **Setting:** Clinic (primary) **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS score at screening (SD) = 16.6 (4.3) **N (number randomised):** 192 **Mean age (years):** 29.7 **Inclusion criteria:** i) DSM-IV diagnosis of depression; ii) 37–42 week pregnancy; iii) infant birth-weight 2.5 kg and above; iv) no congenital abnormality; v) no major health problem; vi) no concurrent major psychiatric disorder. **Exclusion criteria:** i) depression affecting competence to give informed consent (for example psychotic depression); ii) risk requiring crisis management; iii) participation in other psychological programmes; iv) significant difficulty with English.
Interventions	**Experimental intervention 1** **Name:** CBT **Description:** Group-based CBT was developed by adapting Lewinsohn's Coping with Depression Course. The course was modified to meet the needs of new mothers. Modifications included: the addition of partner sessions and modules on family of origin issues; adaptation to the order of sessions so that relaxation is deferred in favour of the earlier introduction of pleasant activities and time management; adaptation to the content to make it less demanding in terms of time and information processing (for instance, by providing techniques like 'relaxation-on-the-run') **Format:** Group **Group size:** 5-10 **Sessions:** 11 **Frequency (number of doses per week):** 1

	Duration (weeks): 12 **Provider:** Senior therapist **Experimental intervention 2** **Name:** Counselling (group) **Description:** This involved counselling designed for depression and utilized supportive listening, history taking, problem clarification, goal formation, problem solving, partner sessions and group process **Format:** Group **Group size:** 5-10 **Sessions:** 11 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Senior therapist **Experimental intervention 3** **Name:** Counselling (individual) **Description:** This had the same content as the group-based counselling including partner sessions, but was delivered on a one-to-one basis **Format:** Individual **Group size:** N/A **Sessions:** 11 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Senior therapist **Control intervention** **Name:** Treatment as usual **Description:** Case-managed by their maternal and child health nurse and referred to other agencies/services as necessary, as normally happens where specialized PND programs are unavailable **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (BDI>16); Social support (SPS); Drop-out **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	National Health & Medical Research Council and Austin Hospital Medical Research Foundation
Limitations	1. Risk of selection bias is unclear/unknown due to an unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method is unclear as the paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.36 MILGROM2011A

Study ID	MILGROM2011A
Bibliographic reference	Milgrom J, Schembri C, Ericksen J, Ross J, Gemmill AW. Towards parenthood: an antenatal intervention to reduce depression, anxiety and parenting difficulties. Journal of Affective Disorders. 2011;130:385-394.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported (workbook) **Country:** Australia
Participants	**Timing:** Antenatal **Baseline symptoms:** Mean EPDS score at baseline = 9. Participants with both high and low scores on depression and anxiety scales **N (number randomised):** 143 **Mean age (years):** 32.3 **Inclusion criteria:** i) 20–32 weeks pregnant; ii) scored ≥13 on the EPDS and/or RAC; iii) able to understand written English; iv) no presence of psychotic symptoms or extreme levels of distress requiring crisis management **Exclusion criteria:** i) presence of psychotic symptoms; ii) extreme levels of distress requiring crisis management
Interventions	**Experimental intervention** **Name:** Towards Parenthood intervention **Description:** The Towards Parenthood intervention consisted of a self-help workbook comprising nine units — eight to be read during pregnancy and one to be read following the birth **Format:** Individual **Group size:** N/A **Sessions:** 0 sessions of contact with healthcare professional (9 workbook units) **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Self **Control intervention** **Name:** Treatment as usual **Description:** Community networking pamphlet highlighting the importance of establishing support networks and listing contacts for relevant services and an information booklet about emotional health during pregnancy and early parenthood developed by beyondblue and case-managed by their midwife and/or GP as occurs routinely. **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 8 **Provider:** Self, midwife and GP
Outcomes	**Outcomes used:** Depression symptomatology (BDI-II=>14); Anxiety symptomatology (Depression Anxiety Stress Scales short form [DASS]=>8); Parental stress symptomatology (Parenting Stress Index [PSI]=>260) **Outcomes not used:** Data not reported for any continuous outcome measures. Data not extracted for DASS Stress subscale as PSI also reported and this is

	more widely used scale
Study design	Randomised controlled trial (RCT)
Source of funding	beyondblue Victorian Centre of Excellence in Depression and Related Disorders
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as data not reported for any continuous measures
Notes	Protocol registered: ACTRN012606000263594

1.11.37 MILGROM2011B

Study ID	MILGROM2011B
Bibliographic reference	Milgrom J, Holt CJ, Gemmill AW, Ericksen J, Leigh B, Buist A, et al. Treating postnatal depressive symptoms in primary care: a randomised controlled trial of GP management, with and without adjunctive counselling. BMC Psychiatry. 2011b;11:95.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (primary) or hospital **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% = >13 EPDS. Mean baseline EPDS=16.98, SD 4.49. Mean baseline BDI-II=29.14, SD 10.12 **N (number randomised):** 68 **Mean age (years):** 31.5 **Inclusion criteria:** i) women scoring = >13 on EPDS; ii) infant aged 6 weeks to 4 months **Exclusion criteria:** i) insufficient English; ii) psychotic symptoms; iii) need for immediate crisis management
Interventions	**Experimental intervention 1** **Name:** CBT (nurse-led) + GP training **Description:** Enhanced TAU (GP training [see below]) plus nurse-led CBT. The sessions focused on: psycho-education about PND; goal setting and problem solving; behavioural interventions (for example encouraging pleasant activities, relaxation); basic cognitive techniques (for example link between thoughts and feelings, challenging unhelpful beliefs and thoughts). Additional components included: the partner relationship, social support and the mother-baby relationship. The Overcoming Postnatal Depression manual provided detailed step-by-step, prompted, six-session content. **Format:** Individual **Group size:** N/A **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Nurse **Experimental intervention 2**

	Name: CBT (psychologist-led) + GP training **Description:** Enhanced TAU (GP training [see below]) plus psychologist-led CBT. The content of this intervention was the same as nurse-led CBT but delivered by an experineced psychologist at a hospital psychology department **Format:** Individual **Group size:** N/A **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Psychologist **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Each participant's GP received training (supported by detailed prinyed materials) to enhance their ability to manage PND. Training involved systematically working through a training manual covering: screening; diagnosis with DSM-IV; risk assessment and management; engagement; a biopsychosocial model of PND; medication during lactation; common patient concerns; onward referral; principles of treatment (including supportive counselling strategies and cognitive-behavioural strategies). Telephone consultation with a psychiatrist was available to provide additional advice on medication for PND. **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** Not reported **Provider:** GP
Outcomes	**Outcomes used:** Depression symptomatology (BDI-II=>14); Depression mean scores (BDI-II); Drop-out **Outcomes not used:** Data not reported for Depression Anxiety and Stress Scales (DASS 21 SF) – Stress and Anxiety subscales
Study design	Randomised controlled trial (RCT)
Source of funding	Victorian Centre of Excellence in Depression and Related Disorders and the Royal Australian and New Zealand College of Psychiatrists
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as data not reported for Depression Anxiety and Stress Scales (DASS 21 SF) – Stress and Anxiety subscales
Notes	Protocol registered: NCT01002027 Missing outcome data requested but author response pending

1.11.38 MISRI2000

Study ID	MISRI2000
Bibliographic reference	Misri S, Kostaras X, Fox D, Kostaras D. The impact of partner support in the treatment of postpartum depression. Canadian Journal of Psychiatry. 2000;45:554-558.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the

	participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinding of outcome assessor unclear **Setting:** Clinic (primary) **Country:** Canada
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-IV Major depressive disorder with postpartum onset assessed using Mini-Neuropsychiatric Interview (MINI). Baseline EPDS mean: 17.65 (SD 3.5) **N (number randomised):** 29 **Mean age (years):** 33.2 **Inclusion criteria:** i) met the DSM-IV criteria for major depression with postpartum onset assessed using MINI; ii) married or cohabiting; iii) Edinburgh Postnatal Depression Scale (EPDS) score of 12 or more at the start of the study **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Co-parenting intervention **Description:** Co-parenting intervention with partners attending 50% of intervention sessions and positive interaction between the couple was promoted through the therapist focusing on postpartum issues such as helping with the baby and participating in housework and other related tasks **Format:** Individual **Group size:** N/A **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Therapist **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Participants attended sessions alone and at each visit the woman's mood was assessed and pharmacological treatment was reviewed **Format:** Individual **Group size:** N/A **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Therapist
Outcomes	**Outcomes used:** Depression diagnosis (MINI); Depression mean scores (EPDS); Psychological distress (Kellner Symptom Scale) **Outcomes not used:** Data not extracted for partner outcomes. Data not extracted for follow-up as <9 weeks post-intervention. Data not extracted for Dyadic Adjustment Scale (DAS)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to an unclear randomisation method and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel

	3. Risk of detection bias is unclear for depression diagnosis (MINI) as blinding of outcome assessment is unclear 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.39 MORRELL2009A/2009B/2011/BRUGHA2011

Study ID	MORRELL2009A/2009B/2011/BRUGHA2011
Bibliographic reference	Morrell CJ, Warner R, Slade P, Dixon S, Walters S, Paley G, et al. Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial. Health Technology Assessment. 2009a;13:No. 30. Morrell CJ, Slade P, Warner R, Paley G, Dixon S, Walters SJ, et al. Clinical effectiveness of health visitor training in psychologically informed approaches for depression in postnatal women: pragmatic cluster randomised trial in primary care. BMJ. 2009b;338:a3045. Morrell CJ, Ricketts T, Tudor K, Williams C, Curran J, Barkham M. Training health visitors in cognitive behavioural and person-centred approaches for depression in postnatal women as part of a cluster randomised trial and economic evaluation in primary care: the PoNDER trial. Primary Health Care Research and Development. 2011;12:11-20. Brugha TS, Morrell CJ, Slade P, Walters SJ. Universal prevention of depression in women postnatally: cluster randomized trial evidence in primary care. Psychological Medicine. 2011;41:739-748.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Baseline EPDS in 'depressed' subset=15.2 (3.0) **N (number randomised):** 595 **Mean age (years):** 30.9 **Inclusion criteria:** i) antenatal women registered with participating practices in the Trent region; ii) aged 18 or more; able to give informed consent; iii) for the 'depressed' subsample EPDS=>12 **Exclusion criteria:** i) severe mental health problems.
Interventions	**Experimental intervention 1** **Name:** CBT **Description:** The cognitive behavioural training emphasised a normalising rationale and the identification of unhelpful patterns of behaviours, perceptions or thoughts in the owman's life, in order to help the woman to change these herself **Format:** Individual **Group size:** N/A **Sessions:** 8

	Frequency (number of doses per week): 1 **Duration (weeks):** 8 **Provider:** Health visitor **Experimental intervention 2** **Name:** Person centred approach **Description:** The person-centred training used the three principles of the actualising tendency, a non-directive attitude and the necessary and sufficient conditions of change. PCA was based on the idea that opportunities to explore difficulties with another, who listens non-judgementally and reflects empathically, allows a person to feel validated as a person and facilitates their abilities to manage their distress and find their own solutions. **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Health visitor **Control intervention** **Name:** Treatment as usual **Description:** General practitioners, midwives, and hospital obstetricians meet women early in pregnancy to plan care. Care is then given by a midwife, shared between the midwife and possibly a general practitioner, or otherwise. Consultant led care is based on clinical need. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8 **Provider:** Midwife, GP and/or obstetrician (according to individual need)
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS=>12); mean score (EPDS); physical health (SF-12 PCS); general mental health (SF-12 MCS); wellbeing (CORE-OM); risk of self-harm (CORE-OM); life functioning (CORE-OM); anxiety (STAI); parental stress (PSI) **Outcomes not used:** 12- and 18-month follow-up data not reported. Data not extracted for CORE-OM symptoms (or CORE-OM total score) as SF-12 MCS also reported and this is more widely used measure of general mental health, data also not extracted for SF-6D as not clear what this outcome measures. Data not extracted for SF-12 PCS as outcome outside scope. Life Events Questionnaire (LEQ) not used. PSI subscales not extracted as total score more widely reported
Study design	Randomised controlled trial (RCT)
Source of funding	NHS research and development health technology assessment programme
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports available case and although ITT (WCS) computed whereever possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as 12- and 18-month outcome data are not reported
Notes	Protocol registered: ISRCTN92195776

1.11.40 MULCAHY2010

Study ID	MULCAHY2010
Bibliographic reference	Mulcahy R, Reay RE, Wilkinson RB, Owen C. A randomised control trial for the effectiveness of group interpersonal psychotherapy for postnatal depression. Archives of Women's Mental Health. 2010;13:125-139.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% met DSM-IV criteria for major depression determined using Millon Clinical Multiaxial Inventory-III and HAMD-D = > 14. Baseline EPDS mean=16.8 (SD 2.7). Baseline BDI-II mean=28.9 (SD 6.8; severe range of symptom severity). Baseline HAM-D mean=15.9 (SD 2.1; moderately depressed range) **N (number randomised):** 57 **Mean age (years):** 32.2 **Inclusion criteria:** i) diagnosis of postnatal depression based on DSM-IV criteria for major depression (assessed using Millon Clinical Multiaxial Inventory-III [MCMI-III]) and HAM-D score = >14; ii) infant aged 12 months or younger **Exclusion criteria:** i) presence of severe personality disorder, acute psychosis, suicidality, significant substance abuse, child abuse or neglect
Interventions	**Experimental intervention** **Name:** Group interpersonal psychotherapy **Description:** Intervention based on interpersonal psychotherapy, modified for a group setting. IPT is a short-term psychotherapy that specifically targets interpersonal relationships. In particular, the social role transitions, conflicts and issues with key relationships, as well as grief and loss issues associated with becoming a parent (Stuart and Robertson 2003). Adaptations of IPT for groups included use of the processes of 'modelling' and 'social reinforcement' by group members as well as group brainstorming **Format:** Group **Group size:** Not reported **Sessions:** 11 **Frequency (number of doses per week):** Not reported **Duration (weeks):** 8 **Provider:** The two principal researchers **Control intervention** **Name:** Treatment as usual **Description:** Essentially this condition encompassed all of the options for support, assistance and treatment for postnatal depression currently being accessed by women in the Australian Capital Territory (ACT) community. Thus, potential treatment options included antidepressant medication, natural remedies, nondirective counselling, Maternal and Child Health Nurse support, community support groups, and individual psychotherapy or group therapy already provided in the community (either publicly or privately). Women were given written and verbal information on the range of local services available.

	Format: Not reported **Group size:** Not reported **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS non-response [EPDS>13 and <4 point decrease]); Depression mean score (EPDS); Social support (ISEL); Mother-infant attachment (MAI); Service utilisation **Outcomes not used:** Data not reported for depression symptomatology (EPDS recovery >4 point decrease and EPDS<13) at 3-month follow-up. Data not extracted for 4-week time point as mid-treatment and data not extracted for the HAM-D or BDI-II as the EPDS more widely reported. Data not extracted for Dyadic Adjustment Scale (DAS)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports available case and although ITT (WCS) computed whereever possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data not reported for depression symptomatology (EPDS recovery >4 point decrease and EPDS<13) at 3-month follow-up
Notes	None

1.11.41 MUNOZ2007/URIZAR2011

Study ID	MUNOZ2007/URIZAR2011
Bibliographic reference	Munoz RF, Le H-N, Ippen CG, Diaz MA, Urizar Jr. GG, Soto J, et al. Prevention of postpartum depression in low-income women: development of the Mamas y Bebes/Mothers and Babies course. Cognitive and Behavioral Practice. 2007;14:70-83. Urizar Jr. GG, Muñoz RF. Impact of a prenatal cognitive-behavioral stress management intervention on salivary cortisol levels in low-income mothers and their infants. Psychoneuroendocrinology. 2011;36:1480-1494.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or unclear blinding of outcome assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Mean baseline CES-D = 16.4 **N (number randomised):** 45 **Mean age (years):** 24.9 **Inclusion criteria:** i) at least 18 years of age; ii) were between 12 to 32 weeks

	pregnant; iii) had verbal and written fluency in either Spanish or English; iv) did not have any current major medical or substance abuse problems; v) A past history of major depressive episodes (MDE) and/or ≥16 on the Center for Epidemiologic Studies Depression Scale (CES-D) **Exclusion criteria:** i) women who screened positive for a current major depression episode per DSM-IV criteria
Interventions	**Experimental intervention** **Name:** Mothers and Babies (MB) CBT-infomred psychoeducation group **Description:** Mamás y Bebés/Mothers and Babies: Mood and Health Project. The manual was designed to address the socio-cultural issues relevant to a low-income, culturally diverse population. Its intent was to teach participants to recognize which thoughts, behaviors, and social contacts had influence on their mood, the effect of mood on health, and the benefits of strengthening maternal-infant bonding **Format:** Group **Group size:** 3-8 **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Faculty, postdoctoral fellows, advanced doctoral graduate students in clinical psychology **Control intervention** **Name:** Treatment as usual **Description:** Usual medical care and were provided with information on locally available social services,upon request, during the 12-week period **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 12 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (MMS); Depression mean scores (EPDS); Parental strss (salivary cortisol levels and VAS mean score); Negative mood (PANAS); Infant stress (salivary cortisol levels and mean VAS scores) **Outcomes not used:** Data not extracted for 6-month postpartum follow-up (overlap with 12-month follow-up). Data not reported for post-intervention EPDS or MDE incidence or 6-month infant stress rating. Data not extracted for follow-up CES-D as the EPDS more widely reported
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Mental Health (MH59605)
Limitations	1. High risk of selection bias due to statistically significant baseline/mid-treatment difference in average maternal salivary cortisol levels (0.62 in intervention group and 0.75 in control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of detection bias is unclear/unknown for the cortisol levels outcome measure as the blinding of outcome assessment is unclear 4. High risk of selective reporting bias as data not reported for post-intervention EPDS or MDE incidence or 6-month infant stress rating
Notes	None

1.11.42 NEUGEBAUER2006

Study ID	NEUGEBAUER2006
Bibliographic reference	Neugebauer R, Kline J, Markowitz JC, Bleiberg KL, Baxi L, Rosing MA, et al. Pilot randomized controlled trial of interpersonal counseling for subsyndromal depression following miscarriage. Journal of Clinical Psychiatry. 2006;67:1299-1304.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessment **Setting:** Telephone **Country:** US
Participants	**Timing:** Post-miscarriage **Baseline symptoms:** Inclusion criteria: HAM-D-17>7. Baseline HAM-D-17 mean: 16.5 (SD 6.3) **N (number randomised):** 19 **Mean age (years):** 29.7 **Inclusion criteria:** i) women seeking medical care for miscarriage from October 2001 to April 2002 in the emergency departments, the clinics, or the private practice settings at New York-Presbyterian Medical Center in Manhattan and St. Barnabas Hospital in the Bronx, New York; ii) age = >18 years old; iii) English- or Spanish- speaking; iv) reachable by telephone; v) had a medically documented pregnancy loss within 18 weeks prior to baseline interview; vi) reported at least mildly elevated depressive symptoms (HAM-D-17>7) **Exclusion criteria:** i) suicidality; ii) current major depressive disorder (assessed using SCID); iii) substance abuse; iv) history of psychosis; v) life threatening physical illness; vi) mental retardation; vii) refusal to have sessions audio-taped
Interventions	**Experimental intervention** **Name:** Interpersonal Counselling (IPT; Telephone) **Description:** Participants received telephone-based post-miscarriage counselling based on IPT principles. Intervention content included a brief review of depressive symptoms and psychoeducation about depression, exploration of established problem area/s and techniques for solving interpersonal difficulties. Sessions also addressed reproductive history and prior losses in order to increase counsellor-participant rapport **Format:** Individual **Group size:** N/A **Sessions:** 1-6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Psychiatric social worker or psychotherapist **Control intervention** **Name:** Treatment as usual **Description:** Treatment as usual involved any lay counselling or professional care women sought on their own initiative **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported

	Duration (weeks): Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression mean scores (HAM-D-17); Functional impairment (Medical Outcomes Study Questionnaire) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Independent Investigator Award 001395 from the National Alliance for Research on Schizophrenia and Depression, Great Nek, N.Y.; and grant NIII 1 R03 MH59179-01A1 from the National Institutes of Health, Bethesda, Md.
Limitations	1. High risk of selection bias due to unclear randomisation method and allocation concealment and baseline differences between groups in ethnicity (80% Hispanic in intervention group and 44% in TAU) and Hispanic ethnicity was associated with primary outcome with higher depression scores in Hispanic group 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.43 NIKCEVIC2007

Study ID	NIKCEVIC2007
Bibliographic reference	Nikcevic AV, Kuczmierczyk AR, Nicolaides KH. The influence of medical and psychological interventions on women's distress after miscarriage. Journal of Psychosomatic Research. 2007;63:283-290.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (secondary) **Country:** UK
Participants	**Timing:** Post-miscarriage **Baseline symptoms:** Baseline HADS Anxiety mean: 8.1 (SD 2.7) **N (number randomised):** 80 **Mean age (years):** 35.25 **Inclusion criteria:** i) women attending for a routine scan at 10–14 weeks of gestation and found to have a missed miscarriage **Exclusion criteria:** i) women with a history of perinatal death, elective termination for fetal abnormality and recurrent miscarriage; ii) inability to speak and read English fluently; iii) those under current psychological or psychiatric care.
Interventions	**Experimental intervention** **Name:** Psychological counselling (single session) **Description:** Women received a 20-minute consultation with an obstetrician during which results and implications of medical investigations ascertaining causes of missed miscarriage, aspects of general health and planning of future pregnancies were discussed. The intervention group then received an additional 50-minute single counselling session with a psychologist. The counselling was broadly based on the cognitive therapy framework. The main

	aims of the counselling were: to express feelings regarding loss; normalize expressed emotions; exposure to memories (for instance, going over and describing scan images), cognitive restructuring (in cases of self-blame), and reframing and reorganising of the experience in the context of information about the causes of the miscarriage. Worries about future reproduction attempts were also discussed **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session **Provider:** Obstetrician and psychologist **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Women received a 20-minute consultation with a obstetrician during which results and implications of medical investigations ascertaining causes of missed miscarraige, aspects of general health and planning of future pregnancies were discussed **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session **Provider:** Obstetrician
Outcomes	**Outcomes used:** Anxiety mean scores (HADS); Depression mean scores (HADS); Self-blame (study-specific scale); Drop-out **Outcomes not used:** Grief (Texas Grief Inventory); Worry concerning future pregnancies; Quantitative experience of miscarraige care (as no control group data)
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the Fetal Medicine Foundation (Charity No: 1037116)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.44 OHARA2000

Study ID	OHARA2000
Bibliographic reference	O'Hara MW, Stuart S, Gorman LL, Wenzel A. Efficacy of interpersonal psychotherapy for postpartum depression. Archives of General Psychiatry. 2000;57:1039-1045.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or non-blind outcome assessment

	Setting: Not reported **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-IV major depression by SCID for DSM-IV & HRSD >=12. Baseline HRSD mean=19.6 (SD 3.2). Baseline BDI mean=23.3 (SD 5.0) **N (number randomised):** 120 **Mean age (years):** 29.6 **Inclusion criteria:** i) at least 18 years old; ii) Married or living with a partner for at least 6 months; ii) met criteria for depression on the IDD and who met DSM-IV criteria for a major depressive eposode and had a minimum socre of 12 on the amended 17-item version of the HRSD **Exclusion criteria:** i) lifetime history of organic brain syndrome, schizophrenia, mental retardation, antisocial personality, or bipolar disorder; ii) current diagnosis of alcohol or substance abuse, psychotic depression, serious eating disorders, OCD, panic disorder, somatization disorder, or 3 or more schizotypal fatures
Interventions	**Experimental intervention** **Name:** Interpersonal psychotherapy **Description:** Manualised and goal-focused IPT. Initial sessions concerned with identifying depression as a medical disorder afflicting the patient, placing depression in an interpersonal context, reviewing the patient's current and past interpersonal relationships, and relating problematic aspects of these relationships to the patient's depression. The therapist and patient collaboratively identified the IPT problem areas most related to the episode and set treatment goals. During the intermediate sessions the therapist focused on the interpersonal difficulties identified by the patient. In the final session the therapist reinforced the patient's sense of competence in overcoming depression, discussed plans for termination of therapy, and worked with the patient to develop plans should the depression recur. **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Doctoral psychotherapist **Control intervention** **Name:** Waitlist condition **Description:** Fortnightly contact either for outcome assessment or via phone to check suicide risk/ability to wait for treatment **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 12 **Provider:** N/A
Outcomes	**Outcomes used:** Drop-out; Depression diagnosis (SCID); Depression symptomatology (BDI=>10); Depression mean scores (BDI); Life functioning (SAS) **Outcomes not used:** Data not used for 4 or 8-week follow-ups as mid-treatment. Data not used for Postpartum Adjustment Questionnaire (PPAQ) or Dyadic Adjustment Scale (DAS). Data not used for the HRSD as BDI more

	widely reported
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH MH50524
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of detection bias for depression diagnosis (SCID) outcome due to non-blind outcome assessment 3. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.45 OMAHEN2013A

Study ID	OMAHEN2013A
Bibliographic reference	O'Mahen HA, Woodford J, McGinley J, Warren FC, Richards DA, Lynch TR, et al., Internet-based behavioral activation – treatment for postnatal depression (Netmums): a randomized controlled trial. Journal of Affective Disorders. 2013;150:814-822.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Internet **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% >12 on EPDS **N (number randomised):** 910 **Mean age (years):** 32.3 **Inclusion criteria:** i) women who were members of Netmums; ii) aged 18 or over; iii) suffering from depressive symptoms; iv) who had given birth within the past 12 months; v) women who scored greater than 12 on the EPDS **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Postnatal Internet Behavioural Activation **Description:** The treatment was adapted for postnatal, online delivery from the manual developed for Behavioral Activation (Addis and Martell, 2004). The overall goal of BA is to re-engage participants with stable and diverse sources of positive reinforcement from their environment and to develop depression management strategies for future use. The treatment focused on helping mothers achieve a balance in valued activities in the context of competing and unpredictable demands. This is accomplished through scheduling and reducing the frequency of negatively reinforced avoidant behaviors. Sessions could be customized with links to Netmums' cache of online parenting and mother related resources and activities (for example, mother–infant activities, managing infant sleep). For example, in the 'mum friends' session, women were pointed to Netmums' 'meet a mum' feature, which links local mothers together who would like to meet face-to-face

	Format: Individual **Group size:** N/A **Sessions:** 1-2 (median support sessions); 11 (internet sessions) **Frequency (number of doses per week):** Not reported **Duration (weeks):** 15 **Provider:** Self and support provided by online chat room moderated by parent supporters and supervised by specialist health visitors **Control intervention** **Name:** Treatment as usual **Description:** The TAU condition was allowed to vary as per usual practice. Women in both groups had access to Netmums' general depression chat room throughout the course of the study. This chat room was monitored by parent supporters and specialist health visitors **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 15 **Provider:** Not reported
Outcomes	**Outcomes used:** Reliable and clinically significant improvement in depression symptomatology (EPDS>12); Depression mean scores (EPDS) **Outcomes not used:** Depression symptomatology (EPDS>12) as reliable and clinically significant improvement in depression symptomatology is more meaningful outcome
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute for Health Research Collaborations for Leadership in Applied Health Research and Care
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.46 OMAHEN2013B

Study ID	OMAHEN2013B
Bibliographic reference	O'Mahen H, Himle JA, Fedock MA, Henshaw E, Flynn H. A pilot ramdomised controlled trial of cognitive behavioural therapy for perinatal depression adapted for women with low incomes. Depression and Anxiety. 2013;30:679-687.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** UK
Participants	**Timing:** Antenatal and postnatal

	Baseline symptoms: 100% scored = >12 on EPDS and met the DSM-IV criteria (SCID) for MDD **N (number randomised):** 55 **Mean age (years):** 27 **Inclusion criteria:** i) age 18 or older; ii) 24 or more weeks pregnant; iii) not currently receiving any treatment for depression; iv) scoring = >12 on EPDS and meeting DSM-IV criteria (assessed using SCID) for MDD **Exclusion criteria:** i) did not speak English; ii) did not plan to return to the clinic for additional care (for example, moving out of the area); iii) suffered from a cognitive disability or any psychotic disorder; iv) met criteria for current alcohol/drug abuse or dependence.
Interventions	**Experimental intervention** **Name:** CBT-modified **Description:** The mCBT intervention consisted of up to twelve 50-min individual sessions of CBT, adapted for the perinatal period. mCBT included an initial engagement session, which integrated Motivational Interviewing (MI),and three treatment modules: Behavioral Activation (BA), Cognitive Restructuring (CR), Interpersonal Support (IS). The first (engagement) session consisted of: (1) an initial perinatal specific assessment; (2) CBT conceptualization tailored to the woman's individual treatment goals; (3) psychoeducation about perinatal depression and psychotherapy; and (4) engagement strategies to identify and alleviate potential psychological and practical barriers. Throughout the engagement session, MI was used at any point in the interaction that pertained to behavior change, including ambivalence or motivation about behavior change. Consistent with previous CBT recommendations, women proceeded to the BA module. Specific BA techniques included the use of a functional analytical approach to develop an understanding of behaviors that interfere with meaningful, goal-oriented behaviors and included self-monitoring, identifying "depressed behaviors," developing alternative goal-oriented behaviors, and scheduling. The mCBT manual also included an appendix with perinatal specific materials and skills (for example, labor and delivery, sleep) that could be used as tools to support the work in the other modules. Each week women were asked to complete either written or verbally agreed treatment exercises in-between sessions **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Masters and doctoral level social workers and psychologists **Control intervention** **Name:** Treatment as usual **Description:** The group were given feedback about their depression status from an on-site social worker, psychoeducational materials about perinatal depression, and local referral information about psychotherapy and case management. Continued to receive midwife/obstetrical care as normal. Risk was assessed at each interview point **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported

	Provider: Social worker, midwives
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (BDI-II=>14; Depression mean score (BDI-II) **Outcomes not used:** Measures of adherence, barriers and activation (BADS) were not used. For depression symptomatology the reliable and significant change was not extracted as only reported for post-treatment and not follow-up
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH 5R34MH076219
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.47 OMAHEN2013C

Study ID	OMAHEN2013C
Bibliographic reference	O'Mahen HA, Richards DA, Woodford J, Wilkinson E, McGinley J, Taylor RS, et al. Netmums: a phase II randomized controlled trial of a guided internet behavioural activation treatment for postpartum depression. Psychological Medicine. 2013; Oct 23:1-15. [Epub ahead of print]
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Internet **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** ICD-10 criteria for major depressive disorder; EPDS = 20.7 (2.3) **N (number randomised):** 83 **Mean age (years):** Not reported **Inclusion criteria:** i) >18 years old; ii) had given birth to a live baby in the last year; iii) scored greater than 12 on the Edinburgh Postnatal Depression Scale (EPDS) and met ICD-10 criteria for major depressive disorder; iv) did not experience substance abuse, psychosis; v) spoke English **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** NetmumsHWD **Description:** Modified 12-session treatment course consisted of a core BA module (five sessions) and relapse prevention session. Women also chose two optional modules from a list of possible six. All modules followed the BA functional analytic framework. The content included interactive exercises paired with extensive worked examples. **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported

	Provider: Self and mental health workers (IAPT trainees) **Control intervention** **Name:** Treatment as usual **Description:** Allowed to vary as per usual practice. Women in both groups had access to Netmums' general depression chat room throughout the course of the study. The chat room is moderated by health visitors and parent supporters who provid email/chat room posting support and advice for depression **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS>12) and mean scores (EPDS); Anixety mean scores (GAD-7); Social functioning (Social Adjustment Scale [WASAS]; Social support (Social Provision Scale [SPS]); Postnatal bonding (Postnatal Bonding Questionnaire [PBQ]); Health service utilization (Adult Service Use Schedule [AD-SUS]); Drop-out **Outcomes not used:** Data not reported for 6-month follow-up
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for the SouthWest Peninsula
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data not reported for 6-month follow-up
Notes	None

1.11.48 ORTIZCOLLADO2014

Study ID	ORTIZCOLLADO2014
Bibliographic reference	Ortiz Collado MA, Saez M, Favrod J, Hatem M. Antenatal psychosomatic programming to reduce postpartum depression risk and improve childbirth outcomes: a randomized controlled trial in Spain and France. BMC Pregnancy and Childbirth. 2014;14:22.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital **Country:** Spain and France
Participants	**Timing:** Antenatal **Baseline symptoms:** Baseline EPDS mean=10.7 (SD 4.3) **N (number randomised):** 184 **Mean age (years):** 29.3

	Inclusion criteria: i) couples identified as middle or low socioeconomic status (based on income, occupational category and type of employment contract, an indicator of job security); ii) women who were pregnant with gestational age ≤ 20 weeks; iii) women with a moderate to high risk of postnatal depresison (assessed using the Righetti-Veltema et al. [2006] anetnatal interview]; iv) women with no more than two children; v) women without organic serious physical pathology; vi) no psychiatric diagnosis; vii) no alcohol or illicit substance abuse; viii) women who understand the language of the study **Exclusion criteria:** i) a current diagnosis of psychiatric disorder or a serious medical condition
Interventions	**Experimental intervention** **Name:** Antenatal psychosomatic programming **Description:** The intervention was based on the Tourné (2002) psychosomatic approach and included women's partners in the group intervention. Intervention content focused on body awareness sensations, construction of an individualized childbirth model, attachment and preparation for parenting (not just for childbirth). Intervention techniques included developing a therapeutic alliance based on the participant's perspective, normalizing antenatal somatic symptoms, developing alternative explanations for their sensations and experience, and connecting somatic symptoms to emotion. Each session has two or more specific objectives as well as exercises, and sessions 5-7 had no set topic but served to answer questions and clarify doubts from previous sessions. Each session consisted of an interactive exchange of information (60%) and practical exercises (40%). Between sessions, a follow-up phone call was included **Format:** Group **Group size:** 6-8 **Sessions:** 10 **Frequency (number of doses per week):** 1 **Duration (weeks):** 10 **Provider:** Nurse-midwife **Control intervention** **Name:** Treatment as usual **Description:** In the control group (CG), participants were free to choose whether or not to participate in standard antenatal education programmes in accordance with the existing protocol at their centre of reference. These programmes offer eight sessions of two hours each during the third term of pregnancy; the focus is childbirth and pregnancy health. No information is included about body sensations or individual experience, neither for men nor women, and no follow-up phone calls are made **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 10 **Provider:** Nurse-midwife
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (EPDS=>12); Depression mean scores (EPDS); Birth outcomes (preterm delivery, birthweight); Parental stress (Stress Events Scale); Social support (FSSQ) **Outcomes not used:** Data not extracted for the Dyadic Adjustment Scale (DASS) or the stress no events subscale
Study design	Randomised controlled trial (RCT)

Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed wherever possible, this was not possible for all outcome measures 4. Risk of selective reporting bias is unclear/unknown 5. High risk of attrition bias as drop-out was higher in the control group (N=34; 37%) than in the intervention group (N=23; 25%)
Notes	None

1.11.49 PINHEIRO2014

Study ID	PINHEIRO2014
Bibliographic reference	Pinheiro RT, Botella L, Quevedo LDA, Pinheiro KAT, Jansen K, Osório CM, et al. Maintenance of the effects of cognitive behavioural and relational constructivist psychotherapies in the treatment of women with postpartum depression: a randomized clinical trial. Journal of Constructuvist Psychology. 2014;27:59-68.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Clinic (secondary) **Country:** Brazil
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% BDI=>12. Baseline BDI: 19.55 (7.46). Baseline BAI: 17.05 (11.77) **N (number randomised):** 60 **Mean age (years):** 26.97 **Inclusion criteria:** i) residence in the urban zome of Petolas; ii) aged over 18 years old; iii) Gave birth to babies in a maternity ward in the city of Petolas between 2004 and 2005; iv) showed symptoms of depression (BDI=>12) **Exclusion criteria:** i) those who showed a risk of suicide or refused to receive interventions; ii) women who had used antidepressants or mood stabilizers
Interventions	**Experimental intervention** **Name:** CBT **Description:** The CBT manual was constructed according to Beck's proposals and was aimed at evaluating and modifying dysfunctional thoughts in order to improve the individual's mood and behaviour **Format:** Individual **Group size:** N/A **Sessions:** 7 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Clinical psychology interns **Control intervention** **Name:** Relational Constructivist Psychotherapy

	Description: Relational Constructivist Psychotherapy draws on George Kelly's (1991) personal construct psychology and is based on the theory that people are able to reinvent themselves through a process of reconstruction. In Relational Constructivist Psychotherapy the therapist takes a collaborative role and it is through the therapeutic relationship and a process of collaborative dialogue that change is constructed. This intervention is different from CBT in that individuals do not fight dysfunctional ideas through confrontation but instead discourse is narrative and reflective which can cause less resistance. The intervention was manualized and the manual was constructed in accordance with the Botella proposal (1995) **Format:** Individual **Group size:** N/A **Sessions:** 7 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Clinical psychology interns
Outcomes	**Outcomes used:** Depression mean score (BDI); Anxiety mean score (BAI); Drop-out **Outcomes not used:** Data could not be extracted for 12-month follow-up or symptomatology (BDI=>12) or diagnosis (MINI)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. High risk of selective rpeorting bias as data could not be extracted for 12-month follow-up or symptomatology (BDI=>12) or diagnosis (MINI)
Notes	None

1.11.50 PRENDERGAST2001

Study ID	PRENDERGAST2001
Bibliographic reference	Prendergast J, Austin M-P. Early childhood nurse-delivered cognitive behavioural counselling for post-natal depression. Australasian Psychiatry. 2001;9:255-259.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** 32% major, 68% minor depression (research criteria in DSM-IV). EPDS mean (SD): CBT 15.9 (2.8); control 13.7 (2.3). N.B. Significant difference

	N (number randomised): 37 **Mean age (years):** 32.2 **Inclusion criteria:** i) women scoring above 12 on the EPDS **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Modified CBT for PND **Description:** A CBT-based work-book that had been prepared for the study. The work-book contained detailed psychoeducation, cognitive monitoring and thought challenging diaries and modules on anxiety management, assertiveness training, self-esteem and pleasant-event scheduling. The work-book was used as a 'prompt' for the ECNs as they worked through the modules with the women. It did not specifically focus on relationships with the infant or spouse but these issues were often covered during cognitive challenging and assertiveness modules **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Early childhood nurses with special training **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Women were offered weekly 20-60 minute appointments at the clinic for non-specific emotional support and mothercraft advice **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Early childhood nurse with no additional training
Outcomes	**Outcomes used:** Depression symptomatology (EPDS>10); Depression mean score (EPDS) **Outcomes not used:** Data not reported for Depression, Anxiety, Stress Scale (DASS) or Parenting Stress Index (PSI). Data was not extracted for mean scores on Montgomery and Asberg Depression Rating Scale (MADRS) as EPDS more widely used
Study design	Randomised controlled trial (RCT)
Source of funding	RANZCP Board of Research grant
Limitations	1. High risk of selection bias due to unclear allocation concealment and statistically significant group difference in baseline mean EPDS score (15.9 in intervention group and 13.7 in control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of bias assoictaed with analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 4. High risk of selective reporting bias as data not reported for Depression, Anxiety, Stress Scale (DASS) or Parenting Stress Index (PSI)
Notes	None

1.11.51 RAHMAN2008

Study ID	RAHMAN2008
Bibliographic reference	Rahman A, Malik A, Sikander S, Roberts C, Creed F. Cognitive behaviour therapy-based intervention by community health workers for mothers with depression and their infants in rural Pakistan: a cluster-randomised controlled trial. Lancet. 2008;372:902-909.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** Pakistan
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 100% met criteria for DSM-IV major depressive episode (SCID). Baseline depression mean scores (Hamilton Depression Rating Scale): 14.6 (3.0) **N (number randomised):** 903 **Mean age (years):** 26.7 **Inclusion criteria:** i) women who were in the 40 Union councils aged 16-45 years; ii) married; iii) in their third trimester of pregnancy; iv) DSM-IV diagnosis of major depressive episode (assessed using SCID) **Exclusion criteria:** i) diagnosis of a serious medical condiiton requiring inpatient or outpatient treatment; ii) pregnancy-related illness (except for common conditions, such as anaemia); iii) substantial physical or learning disability; iv) postpartum or other form of psychosis; v) had infants who were aborted, stillborn, born premature or congenitally disabled, given up for adoption or died in the first year; vi) women who became seriously ill, died or moved residence during the trial
Interventions	**Experimental intervention** **Name:** Thinking Healthy Programme **Description:** The intervention, called the Thinking Healthy Programme, used cognitive behaviour therapy techniques of active listening, collaboration with the family, guided discovery (ie, style of questioning to both gently probe for family's health beliefs and to stimulate alternative ideas), and homework (ie, trying things out between sessions, putting what has been learned into practice), and applied these to health workers' routineractice of maternal and child health education. **Format:** Individual **Group size:** N/A **Sessions:** 16 **Frequency (number of doses per week):** Variable (a session every week for 4 weeks in the last month of pregnancy, three sessions in the first postnatal month, and nine 1-monthly sessions thereafter) **Duration (weeks):** 48 **Provider:** Health visitor **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Mothers in the control clusters received an equal number of visits in exactly the same way as those in the intervention group, but by routinely trained Lady Health Workers.In practice, the Lady Health Workers seldom provide such structured and monitored care in the community. The control

	group thus received what would be regarded as ideal care, which we called enhanced routine care. **Format:** Individual **Group size:** N/A **Sessions:** 16 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Health visitor
Outcomes	**Outcomes used:** Depression diagnosis (SCID); Mean depression score (Hamilton Rating Scale); Life functioning (Global Assessment of Functioning Scale); Social support (Multidimensional Scale for Perceived Social Support); Infant physical health (weight; height; diarrhoea); Optimal care of infant (immunisation); Mother-infant interaction (breastfeeding; play frequency); Drop-out **Outcomes not used:** Data not extracted for 6-month postnatally as mid-treatment. Data not extracted for disability score (Brief Disability Questionnaire)
Study design	Randomised controlled trial (RCT)
Source of funding	Wellcome Trust, UK, through a career development fellowship in tropical medicine awarded to AR. The fellowship was awarded through the Wellcome Trust Tropical Centre at the Liverpool School of Tropical Medicine and hosted by the University of Manchester and the Institute of Psychiatry, Rawalpindi.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures
Notes	Protocol registered: ISRCTN65316374

1.11.52 ROMAN2009

Study ID	ROMAN2009
Bibliographic reference	Roman LA, Gardiner JC, Lindsay JK, Moore JS, Luo Z, Baer LJ, et al. Alleviating perinatal depressive symptoms and stress: A nurse-community health worker randomized trial. Archives of Women's Mental Health. 2009;12:379-391.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** 56% CES-D=>16. Baseline CES-D mean: 19.5 (SD 7.7) **N (number randomised):** 613 **Mean age (years):** Not reported **Inclusion criteria:** i) women who lived in the county with no plans to move within 18 months; ii) were Medicaid eligible; iii) had no pre-existing relationship with a home visiting nurse; iv) were at least 16 years of age; v)

	spoke Spanish or English **Exclusion criteria:** i) diagnosis or treatment for a preexisting mental health condition within the last two years
Interventions	**Experimental intervention** **Name:** Nurse-Community Health Worker home visiting team in the context of a Medicaid enhanced pre/postnatal services (EPS) **Description:** The Nurse-Community Health Worker (Nurse-CHW) team intervention primarily differed from TAU in that it involved 1) the utilization of CHWs with nurses; 2) persistent efforts to directly contact, assess, and engage women in services; 3) intensive relationship-based social support from a CHW (increased program contact); and 4) the targeting of stressors and maternal mental health. Nurses guided the CHW care, led a multidisciplinary team assessment, provided crisis intervention and case management, assessed and managed health problems (including screening for depression), and had periodic office visits with prenatal providers. CHWs provided relationship-based support through phone and face-to-face contacts. **Format:** Individual **Group size:** N/A **Sessions:** 24 **Frequency (number of doses per week):** Variable (every other week during pregnancy, increased up to weekly [if necessary] for the first postnatal month, then two visits per month until six months post birth, and then visits could be reduced to once a month or be maintained at twice a month) **Duration (weeks):** Not reported **Provider:** Nurse-CHW team: A nurse and two CHWs (trained volunteers) **Control intervention** **Name:** Enhanced Treatment as usual **Description:** State-sponsored, Medicaid enhanced prenatal/postnatal services (EPS) provided by professionals, primarily by nurse. Traditional Michigan EPS included home visiting, multidisciplinary planning, transportation, psychosocial counseling, nutritional guidance, and pregnancy and parenting education. **Format:** Individual **Group size:** N/A **Sessions:** 9 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Nurse
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (CES-D); Parental stress (PSI) **Outcomes not used:** Data cannot be extracted for the Rosenberg self-esteem scale, the Multidimensional Scale of Perceived Social Support, or the the total psychological resources index variable as SDs not reported. Data not used for Pearlin Sense of Mastery scale
Study design	Randomised controlled trial (RCT)
Source of funding	Grant R50 MC 00045-04 R2 from the Maternal and Child Health Bureau
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 3. High risk of selective reporting bias as data cannot be extracted for the

	Rosenberg self-esteem scale, the Multidimensional Scale of Perceived Social Support, or the the total psychological resources index variable as SDs not reported
Notes	Protocol registered: ISRCTN65316374

1.11.53 ROUHE2012/SALMELAARO2012

Study ID	ROUHE2012/SALMELAARO2012
Bibliographic reference	Rouhe H, Salmela-Aro K, Toivanen R, Tokola M, Halmesmäki E, et al. Obstetric outcome after intervention for severe fear of childbirth in nulliparous women – Randomised trial. BJOG: An International Journal of Obstetrics and Gynaecology. 2012;120:75-84. Salmela-Aro K, Read S, Rouhe H, Halmesmäki E, Toivanen RM, et al. Promoting positive motherhood among nulliparous pregnant women with an intense fear of childbirth: RCT intervention. Journal of Health Psychology. 2012;17:520-534.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** Finland
Participants	**Timing:** Antenatal **Baseline symptoms:** W-DEQ-A = 113 **N (number randomised):** 371 **Mean age (years):** 29.4 **Inclusion criteria:** i) nulliparous women whose W-DEQ-A score was above the 95th percentile (W-DEQ-A sum score=>100) **Exclusion criteria:** i) manifest psychosis and severe depression
Interventions	**Experimental intervention** **Name:** Psychoeducative Group Therapy **Description:** The intervention method was psychoeducative group therapy. Each session included a focused topic (information about fear of childbirth; hospital routines; birth process and pain relief; preparation for delivery and birth plan) and a 30-minute guided relaxation exercise using a compact audio disk developed for this purpose. This relaxation exercise guided the participants through stages of imaginary delivery in a relaxed state of mind with positive, calming and supportive suggestions. **Format:** Group **Group size:** 6 **Sessions:** 7 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Psychologist **Control intervention** **Name:** Treatment as usual **Description:** 44% received specialised care for fear of childbirth from an obstetrician and/or midwife in a secondary clinic and 56% cared for by community nurses and GPs in primary health care

	Format: Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Obstetrician, midwife, community nurse or GP (according to individual need)
Outcomes	**Outcomes used:** Spontaneous vaginal delivery; Elective caesarean section; W-DEQ-B score **Outcomes not used:** Data not extracted for: VE (vacuum extraction); CS (caesarean section); Emergency CS; Epidural or spinal analgesia; Induction of labour; Bleeding; Stage I length; Stage II length; Gestational age; Birthweight; pH<7.1; Apgar (1 min); Postpartum interventions; Delivery satisfaction; Positive delivery experience
Study design	Randomised controlled trial (RCT)
Source of funding	Grants from the Emil Aaltonen Foundation and the Signe and Ane Gyllenberg Foundation.
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown (paper reports that protocol is registered, NTC01548131, but cannot be found)
Notes	None

1.11.54 SAISTO2001

Study ID	SAISTO2001
Bibliographic reference	Saisto T, Salmela-Aro K, Nurmi J, Könönen T, Halmesmäki E. A randomized controlled trial of intervention in fear of childbirth. Acta Obstet Gyn Scan. 2001; 98: 820-826.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Finland
Participants	**Timing:** Antenatal **Baseline symptoms:** Study-specific questionnaire = >5 affirmative answers or request for caesarean **N (number randomised):** 176 **Mean age (years):** 31.6 **Inclusion criteria:** i) obstetrically low-risk and physically healthy pregnant women; ii) referred to the outpatient clinic of the Department of Obstetrics and Gynecology in Helsinki University Central Hospital because of fear of vaginal delivery; iii) gave five or more affirmative answers on a study-specific fear of childbirth scale or request for cesarean **Exclusion criteria:** i) contraindication to vaginal delivery at the time of randomization (two previous cesareans or vertical incision in previous

	cesarean)
Interventions	**Experimental intervention** **Name:** Psychotherapy **Description:** Therapy in the intensive therapy group consisted of provision of information and conversation regarding previous obstetric experiences, feelings, and misconceptions. The appointments were based on routine obstetric check-ups to assure the normal course of the pregnancy, combined with cognitive therapy, the main principles of which are focus on one target problem involving the active role of the therapist and reformulation of the problem during a limited time. Psychotherapy is reflective action aimed at teaching the patient to see her problem in an altered way (self-reflection) and to change her particular target-problem procedures by cognitive and behavioral exercises. An appointment with the midwife and visits to the obstetric ward were recommended to provide more practical information about pain relief and possible interventions (vacuum, scalp blood sample, etc.) during labor and delivery. All women were allowed to phone researcher or midwife between sessions. Written information was given at the first session regarding the pros and cons of vaginal delivery and of cesarean, as well as information about alternative modes of pain relief available at our hospital. **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 0.4 **Duration (weeks):** 14 **Provider:** Obstetrician (and midwife for one session) **Control intervention** **Name:** Treatment as usual **Description:** Therapy in the conventional therapy group consisted of standard information distribution and routine obstetric check-ups, as well as provision of written information about the pros and cons of vaginal delivery versus cesarean, and the pain relief that is offered at the hospital **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** 0.2 **Duration (weeks):** 12 **Provider:** Obstetrician
Outcomes	**Outcomes used:** Vaginal delivery; Caesarean for psychosocial reasons; Fear of pain in labour (PAS); fear of obstetrician's unfriendly behaviour (PAS); satisfaction with childbirth; feeling safe in childbirth **Outcomes not used:** Paper does not provide data for Revised version of Beck's Depression Inventory, some subscales of the Pregnancy Anxiety Scale, and the revised version of the Personal Concerns scale
Study design	Randomised controlled trial (RCT)
Source of funding	Signe and Ane Gyllenberg Foundation, the Emil Aaltonen Foundation, Helsinki University Central Hospital, and the Academy of Finland
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective rpeorting bias as paper does not provide data for

	Revised version of Beck's Depression Inventory, some subscales of the Pregnancy Anxiety Scale, and the revised version of the Personal Concerns scale
Notes	Data requested, and author reponse pending for: Means and standard deviations for all outcomes measured at all time points. Intent-to-treat analyses.

1.11.55 SALOMONSSON2011

Study ID	SALOMONSSON2011
Bibliographic reference	Salomonsson B, Sandell R. A randomized controlled trial of mother-infant psychoanalytic treatment: I. outcomes on self-report questionnaires and eternal ratings. Infant Mental Health Journal. 2011;32:207-231.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report, blinded and non-blinded outcome assessment **Setting:** Clinic (secondary) **Country:** Sweden
Participants	**Timing:** Postnatal **Baseline symptoms:** Baseline EPDS mean = 11.9 (SD 3.3) **N (number randomised):** 80 **Mean age (years):** 33.6 **Inclusion criteria:** i) mother should express significant concerns regarding herself as a mother, her infant's well-being, or their relationship (assessed using Parent–Infant Relationship Global Assessment Scale and SPSQ); ii) infant under 18 months; iii) duration of the mother's concerns was longer than 2 weeks; iv) mother had a reasonable mastery of the Swedish language **Exclusion criteria:** i) mothers lived outside Stockholm; ii) were still pregnant; iii) had DSM-IV-TR maternal psychosis or substance dependence to an extent that would preclude collaboration
Interventions	**Experimental intervention** **Name:** Mother-infant psychotherapy (MIP) **Description:** Mother-infant psychoanalytic (MIP) treatment uses psychoanalytically oriented techniques. The analyst receives and emotionally processes within him-/herself the infant's distress and communicates it back to the infant in a form that the infant can assimilate. In the MIP method, the mother is always present and is often affected by the infant–analyst interchange. As she witnesses their interaction, she will understand more about the links between her baby's affects and symptoms, which enables her to resume maternal care. For this to occur, the analyst needs to pay close attention to her self-esteem, which often vacillates. **Format:** Individual **Group size:** N/A **Sessions:** 29 **Frequency (number of doses per week):** 2.5 **Duration (weeks):** 12 **Provider:** Psychoanalyst **Control intervention**

	Name: Treatment as usual **Description:** The local child health centre (CHC) is responsible for checkups from birth to 6 years of age. CHC care (CHCC) aims at assisting paernts concerning their children's physical, psychical and social development. This may concern nursing, food, sleep, and other concerns about the child's health. Checkups consist of weighing and measuring the baby, providing inoculations, nutritional advice, scheduled pediatric checkups, and so on. Contemporary CHCC also pays attention to psychological issues of parenthood and offers parental groups, infant massage, or International Child Development Programmes. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression mean score (EPDS); General mental health (SCL-90: GSI); Infant socio-emotional development (ASQ: SE); Mother-infant attachment/interaction (PIR-GAS; EAS); Parental stress (SPSQ) **Outcomes not used:** Data not reported for the maternal nonhostility subscale of the EAS
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of selection bias due to statistically significant baseline difference in the age of infants (4.4 months old in intervention group versus 5.9 months old in TAU group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of detection bias for Parent-Infant Relationship Global Assessment Scale (PIR-GAS) outcome measure due to non-blind outcome assessment 4. High risk of selective reporting bias as data not reported for the maternal nonhostility subscale of the EAS
Notes	Protocol registered: NCT00923559

1.11.56 SILVERSTEIN2011

Study ID	SILVERSTEIN2011
Bibliographic reference	Silverstein M, Feinberg E, Cabral H, Sauder S, Egbert L, Schainker E, et al. Problem-solving education to prevent depression among low-income mothers of preterm infants: a randomized controlled pilot trial. Archives of Women's Mental Health. 2011;14:317-324.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital or home **Country:** US
Participants	**Timing:** Postnatal

	Baseline symptoms: Mean baseline QIDS: 8.96 (mild depression range) **N (number randomised):** 50 **Mean age (years):** 27 **Inclusion criteria:** i) English or Spanish speaking; ii) mothers of infants ≤33 weeks gestation admitted to either of two urban, level III neonatal intensive care units within academic teaching hospitals; iii) mothers had to have evidence of financial hardship based on eligibility for either Women Infants and Children services or state Medicaid. **Exclusion criteria:** i) mothers with psychosis, cognitive limitation, or suicidal ideation; ii) mothers whose infants were not expected to survive; iii) mothers involved with the state's child protective service were excluded only if hospital staff felt it was likely that they would lose custody of their infants.
Interventions	**Experimental intervention** **Name:** Problem Solving Education (PSE) **Description:** PSE is a manualized cognitive behavioral prevention intervention, adapted from Problem-Solving Treatment itself, an evidence-based depression treatment. In a PSE session, educators guide subjects in selecting an objective, measurable problem; then proceed through a series of steps that involve goal setting, brainstorming, and evaluating solutions, choosing a solution, and action planning. Sessions were conducted in locations of subjects' choosing—most often, the hospital or home. **Format:** Individual **Group size:** N/A **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Graduate students (pursuing degrees in social work, public health, and graduate medical sciences) **Control intervention** **Name:** Treatment as usual **Description:** Control mothers received usual hospital services, which included access to a social worker until the time of infants' hospital discharge **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression symptomatology (QIDS=>11); Parental stress (PSS); Social functioning (SAS) **Outcomes not used:** Data were not reported for the Modified PTSD Symptom Scale. Data cannot be extracted for mean number of moderately severe symptom episodes as SD not reported
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Child Health and Human Development (R03HD058075)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data not reported for the

	Modified PTSD Symptom Scale. Data cannot be extracted for mean number of moderately severe symptom episodes as SD not reported
Notes	Data requested, and author response pending for: All means and standard deviations for all outcomes at all time points

1.11.57 SIMAVLI2014

Study ID	SIMAVLI2014
Bibliographic reference	Simavli S, Kaygusuz I, Gumus I, Usluogullari B, Yildirim M, Kafali H. Effect of music therapy during vaginal delivery on postpartum pain relief and mental health. Journal of Affective Disorders. 2014;156:194-199.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Turkey
Participants	**Timing:** During birth **Baseline symptoms:** Baseline EPDS mean=8.3 (SD 1.97) **N (number randomised):** 161 **Mean age (years):** 23.8 **Inclusion criteria:** i) women aged 18-35 years; ii) primiparous with a 37–41 weeks of gestation; iii) singleton pregnant with babies of cephalic presentation and normal birthweight,expected to have normal spontaneous delivery **Exclusion criteria:** i) maternal hypertensive disorders; ii) diabetes mellitus; iii) evidence of intrauterine growth restriction; iv) premature rupture of membranes for longer than 20 hours; v) multiple pregnancies; vi) desired caesarean; vii) receiving analgesic or antipsychotic medications; viii) mothers with hearing difficulties, chronic pain problems, severe dysmenorrhea; ix) inability to understand visual analogue scale or EPDS; x) fetal death in utero; xi) known fetal anomaly
Interventions	**Experimental intervention** **Name:** Music therapy during delivery **Description:** Music therapy during spontaneous vaginal delivery. The intervention started after 2cm cervical dilation and continued to the end of the thord stage of labour. Participants chose their own music but were recommended to select soft, relaxing, regular rhythmic patterns with no extreme changes in dynamics and the tempo of the music was selected to mimic the human heart rate (60-80 beats/min) **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session **Provider:** Self (CD) **Control intervention** **Name:** Treatment as usual **Description:** Treatment as usual during spontaneous vaginal delivery **Format:** Individual **Group size:** N/A

	Sessions: 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS=>13); Depression mean scores (EPDS); Anxiety (VAS); Drop-out **Outcomes not used:** Data only extracted for first measurement as all other assesments <9 week follow-up. Data not extracted for pain or satisfaction with delivery (VAS)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.58 SLEED2013

Study ID	SLEED2013
Bibliographic reference	Sleed M, Baradon T, Fonagy P. New Beginnings for mothers and babies in prison: a cluster randomized controlled trial. Attachment and Human Development. 2013;15:349-367.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessor **Setting:** Prison **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Mean baseline CES-D = 14.5 **N (number randomised):** 195 **Mean age (years):** 26.8 **Inclusion criteria:** i) mother–baby dyads staying on MBUs in the participating prisons during the recruitment period **Exclusion criteria:** i) mother was not sufficiently fluent in English to be able to give informed consent or take part in the research; ii) mother and her baby were known to be due for release before the first follow-up interview
Interventions	**Experimental intervention** **Name:** New Beginnings Programme **Description:** New Beginnings is a manualized attachment-based intervention developed specifically for mothers and babies in prison. The purpose of group was also to help mothers to make links between their babies' behavior and their internal emotional world, to observe their own states of mind, and to think about how their own states of mind and those of their babies are separate but may also influence each other. **Format:** Group

	Group size: 6 **Sessions:** 7 **Frequency (number of doses per week):** 2 **Duration (weeks):** 4 **Provider:** Two parent–infant psychotherapists as facilitators **Control intervention** **Name:** Treatment as usual **Description:** The New Beginnings courses were not held in the control prisons during the study period. The MBU units were otherwise very similar for both the intervention and control groups (HM Prison Service, 2008). Mothers and babies in both groups had access to standard health and social care provision as provided by the prison service **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (CES-D>16); Depression mean score (CES-D); Mother-infant interaction (behavioural observation coded using Coding Interactive Behavior [CIB] scales) **Outcomes not used:** Parent Development Interview (PDI); Mother's Object Relations Scales (MORS)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.59 SPINELLI2003

Study ID	SPINELLI2003
Bibliographic reference	Spinelli MG, Endicott J. Controlled clinical trial of interpersonal psychotherapy versus parenting education program for depressed pregnant women. American Journal of Psychiatry. 2003;160:555-562.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** 100% DSM-IV MDD, HDRS score=>12 **N (number randomised):** 38 **Mean age (years):** 28.7 **Inclusion criteria:** i) English- and Spanish-speaking, physically healthy

	pregnant women between 6 and 36 weeks' gestation; ii) between 18 and 45 years of age; iii) DSM-IV criteria for major depressive disorder and a Hamilton Depression Rating Scale score ≥ 12 **Exclusion criteria:** i) drug/alchohol misuse <6 months previously; ii) acute suicide risk; iii) comorbid Axis I disorder; iv) current antidepressant medication
Interventions	**Experimental intervention** **Name:** IPT-informed psychoeducation for antepartum depression **Description:** Interpersonal psychotherapy was administered over 16 weeks, according to the manual by Klerman et al (1984). The therapy was modified to antenatal depression according to the interpersonal psychotherapy manual (Spinelli, 2010). Discussion of pregnancy issues included grief, roles, interpersonal deficits and also complicated pregnancy, problems specific to gestation such as undesired pregnancy, medical problems associated with pregnancy itself, obstetrical complications, multiple births, and congenital anomalies **Format:** Group **Group size:** Not reported **Sessions:** 16 **Frequency (number of doses per week):** 1 **Duration (weeks):** 16 **Provider:** Therapist **Control intervention** **Name:** Parenting education control programme **Description:** The parenting education program was an attention-placebo condition which varied only the content of the intervention and replaced IPT-informed psychoeducation with non-mental health-focused education and support. Topics included the developmental stages of pregnancy, delivery, parenting, and early childhood, and practical support (as necessary) **Format:** Group **Group size:** Not reported **Sessions:** 16 **Frequency (number of doses per week):** 1 **Duration (weeks):** 16 **Provider:** Therapist
Outcomes	**Outcomes used:** Depression symptomatology (EPDS Treatment Non-Response [no further detail reported]) **Outcomes not used:** Data cannot not be extracted for Maudsley Mother-Infant Interaction Scale. Data not extracted for HRSD and BDI as EPDS more widely reported scale
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH Research Scientist Development Award for Clinicians
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports ITT (LOCF) but trial flow (inclusion criteria applied before or after randomization) and attrition unclear 3. High risk of selective reporting bias as data cannot not be extracted for Maudsley Mother-Infant Interaction Scale
Notes	None

1.11.60 STEIN2006

Study ID	STEIN2006
Bibliographic reference	Stein A, Woolley H, Senior R, Hertzmann L, Lovel M, Lee J, et al. Treating disturbances in the relationship between mothers with bulimic eating disorders and their infants: a randomized, controlled trial of video feedback. American Journal of Psychiatry. 2006;163:899-906.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Blinded outcome assessors **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-IV Eating disorder (assessed by psychiatric interview), 14% bulimia nervosa and 86% eating disorder ot otherwise specified, bulimic type. 60% symptoms of depression (EPDS=>13). Baseline EPDS mean: 14.5. **N (number randomised):** 80 **Mean age (years):** Median=30 **Inclusion criteria:** i) women ages 18–45 years; ii) infants between 4 and 6 months old; iii) Met the DSM-IV diagnostic criteria for an eating disorder, either bulimia nervosa or a similar form of eating disorder of clinical severity, that is, a bulimic subtype of eating disorder not otherwise specified (screened using Eating Disorder Examination and assessed by psychiatric interview) **Exclusion criteria:** i) women with severe comorbid psychiatric disorders
Interventions	**Experimental intervention** **Name:** Video-feedback interactional treatment + guided cognitive behavior self-help for eating disorders **Description:** Combined mother-infant relationship intervention and guided self-help (aimed at the eating disorder). The mother-infant relationship intervention was a video-feedback interactional treatment that was a modification of that developed by Juffer et al (1997). The aim of the treatment was to prevent or reduce mother-infant conflict and enhance mother-child interaction, principally during mealtimes, by facilitating maternal recognition of and responsiveness to her infant's cues and by improving her awareness of the infant's developing skills and needs. The therapist videotaped the mother and infant at home during mealtimes at alternate visits. At the following visits, the therapist and mother watched and discussed extracts selected by the therapist to highlight the infant's signals and exploration and to draw out and enhance the mother's observational skills. In addition guided cognitive behaviour self-help for eating disorders (modified for the postnatal period) was administered during half of each of the first eight sessions. Participants were provided with a self-help manual that explained the programme's six steps. The therapist used a guided self-help stepwise approach to help the mother implement the relevant steps aimed at helping the mother regain control over her eating, reduce vomiting and laxative use, and reduce extreme concerns about shape and body weight. **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** 0.4

	Duration (weeks): 30 **Provider:** Therapists **Control intervention** **Name:** Supportive counselling + guided cognitive behavior self-help for eating disorders **Description:** Combined listening visits and guided self-help (aimed at the eating disorder). The supportive counselling treatment provided the mother with support specifically for herself by means of empathetic listening. It helped the mother reflect on self-selected aspects of her life and related feelings. It aimed to encourage and support any changes she initiated, thereby developing a sense of empowerment and self-confidence.In addition guided cognitive behaviour self-help for eating disorders (modified for the postnatal period) was administered during half of each of the first eight sessions. Participants were provided with a self-help manual that explained the programme's six steps. The therapist used a guided self-help stepwise approach to help the mother implement the relevant steps aimed at helping the mother regain control over her eating, reduce vomiting and laxative use, and reduce extreme concerns about shape and body weight. **Format:** Individual **Group size:** N/A **Sessions:** 11 **Frequency (number of doses per week):** 0.4 **Duration (weeks):** 30 **Provider:** Therapists
Outcomes	**Outcomes used:** Drop-out; Eating disorder diagnosis (Eating Disorder Examination); Mealtime conflict (behavioural observation); Maternal inapprorpiate verbal responses (behavioural observation); Maternal intrusions (behavioural observation); Infant autonomy (behavioural observation); Infant weight-for-age **Outcomes not used:** Data cannot be extracted for any continuous outcomes as medians and IQR reported instead of means and SDs
Study design	Randomised controlled trial (RCT)
Source of funding	Wellcome Trust grant 050892 and funding from the North Central London Research Consortium
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as data cannot not be extracted for any continuous outcomes as medians and IQR reported instead of means and SDs
Notes	Protocol registered: ISRCTN95026274 Data requested, and author response pending, for: All means and standard deviations for all outcomes

1.11.61 SWANSON2009

Study ID	SWANSON2009
Bibliographic reference	Swanson KM, Chen H-T, Graham JC, Wojnar DM, Petra A. Resolution of depression and grief during the first year after miscarriage: a randomized controlled clinical trial of couples-focused interventions. Journal of Women's Health. 2009;18:1245-1257.

Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** US
Participants	**Timing:** Post-miscarriage **Baseline symptoms:** Baseline CES-D mean: 21 **N (number randomised):** 341 **Mean age (years):** 32.4 **Inclusion criteria:** i) both partners agreed to participate; ii) they reported an unplanned, unexpected loss of pregnancy prior to 20 weeks gestation; iii) they could speak and write in English; iv) they were in a self-proclaimed committed relationship; v) geographically accessible; vi) within 3 months of loss **Exclusion criteria:** i) unmarried people; ii) aged <18; iii) only one member of the couple returned the baseline survey
Interventions	**Experimental intervention 1** **Name:** Nurse- led counselling **Description:** The content of all three intervention conditions was based on the Meaning of Miscarriage Model (MMM) and focused on: expressing feelings associated with loss (week 1); identifying who was available to offer support and re-entering the public world as a no-longer expectant couple (week 5); and reviewing personal progress towards resolution and trying again (week 11) . In the Nurse-led counselling (NC) groups couples were visited at home at 1, 5, and 11 weeks post-randomization for 1-hour each time. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 0.3 **Duration (weeks):** 11 **Provider:** Nurse **Experimental intervention 2** **Name:** Self Caring **Description:** The content was based on the MMM model (see above). In the self-care group couples were mailed three 18-min videos accompanied by workbooks (his and her). **Format:** Individual **Group size:** N/A **Sessions:** 0 sessions of contact with healthcare professional (three video and workbook units) **Frequency (number of doses per week):** Not reported **Duration (weeks):** 11 **Provider:** Self **Experimental intervention 3** **Name:** Combined Caring **Description:** The content was based on the MMM model (see above). In the combined nurse-led and self-care group, couples had a single 1-hour session with a nurse who gave couples their first self-care module and encouraged them to use it, followed by two mailed modules. **Format:** Individual **Group size:** N/A

	Sessions: 1 session of contact with healthcare professional (two additional video and workbook units) **Frequency (number of doses per week):** Not reported **Duration (weeks):** 11 **Provider:** Nurse and self **Control intervention** **Name:** Treatment as usual **Description:** No treatment **Format:** N/A **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** N/A **Provider:** N/A
Outcomes	**Outcomes used:** Depression (CES-D) **Outcomes not used:** Grief (Miscarriage Grief Inventory [MGI])
Study design	Randomised controlled trial (RCT)
Source of funding	NIH, National Institute of Nursing Research, 5 R01 NR005343, to K.M.S.
Limitations	1. Risk of selection bias was unclear/unknown due to unconcealed allocation 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as no outcome data reported for: Mood Disturbances (POMS); Coping (Modified Folkman and Lazarus Ways of Coping); Emotional Strength (Swanson); Impact of Miscarriage (Swanson); Couple relationship Mate Caring (Swanson); Support of Mate and Others (Brown); Intimacy (PAIR); Professional Caring (Swanson)
Notes	Protocol registered: NCT00194844 Data requested and provided by author for depression mean scores (CES-D)

1.11.62 TAMAKI2008

Study ID	TAMAKI2008
Bibliographic reference	Tamaki A. Effectiveness of home visits by mental health nurses for Japanese women with post-partum depression. International Journal of Mental Health Nursing. 2008;17:419-427.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Unclear blinding of outcome assessors **Setting:** Home **Country:** Japan
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% DSM-IV major or minor depressive disorder (assessed using SCID-PND) **N (number randomised):** 18 **Mean age (years):** 33.8 **Inclusion criteria:** i) aged 18 years or older; ii) scored >9 on the EPDS; iii)

	DSM-IV major or minor depressive disorder (assessed using SCID-PND) **Exclusion criteria:** i) lived outside the district; ii) had delivered prematurely (<36 weeks); iii) if their infant had any congenital or serious disease; iv) if they did not have a singleton birth; v) if they had received any antidepressant or other specific treatments during the study period
Interventions	**Experimental intervention** **Name:** Home visits **Description:** Active listening, providing support and acceptance of the woman, psycho-education on depressive symptoms, and advice on coping strategies for problematic life issues, including parenting and increasing access to social or family support. The intervention was provided flexibly according to the individual's needs and the nurse's assessment of each woman's self-care level and mental state. **Format:** Individual **Group size:** N/A **Sessions:** 4 **Frequency (number of doses per week):** 0.8 **Duration (weeks):** 5 **Provider:** Mental health nurses **Control intervention** **Name:** Treatment as usual **Description:** Routine care (for example a postpartum visit at home for the newborn with a midwife or a public health nurse and a 4-month post-partum check up at a community-based centre) **Format:** Individual **Group size:** N/A **Sessions:** 2 **Frequency (number of doses per week):** Not reported **Duration (weeks):** 5 **Provider:** Midwife or nurse
Outcomes	**Outcomes used:** Drop-out; Depression diagnosis (SCID-PND); [EoC extracted separately elsewhere] **Outcomes not used:** Data cannot be extracted for any continuous outcomes as medians and IQR reported instead of means and SDs. Data not extracted for 6-week post-intervention (time 3) as <9 weeks follow-up
Study design	Randomised controlled trial (RCT)
Source of funding	Grant-in-Aid for Scientific Research from the Japan Society for the Promotion of Science, and a grant from the University of Hyogo, Hyogo, Japan
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of detection bias is unclear/unknown due to unclear blinding of outcome assessor/s 3. High risk of selective reporting bias as data cannot be extracted for any continuous outcomes as medians and IQR reported instead of means and SDs
Notes	Data requested, and author response pending, for: All means and standard deviations for outcomes (including EPDS and Quality of life scores) at all time points. Details of randomisation- allocation concealment.

1.11.63 TANDON2011/2014/MENDELSON2013

Study ID	TANDON2011/2014/MENDELSON2013
Bibliographic reference	Tandon SD, Perry DF, Mendelson T, Kemp K, Leis JA. Preventing perinatal depression among low-income home visiting clients. Journal of Consulting and Clinical Psychology. 2011;79:707-712. Tandon SD, Leis JA, Mendelson T, Perry DF, Kemp K. Six-month outcomes from a randomized controlled trial to prevent perinatal depression in low-income home visiting clients. Maternal and Child Health Journal. 2014;18:873-881. Mendelson T, Leis JA, Perry DF, Stuart EA, Tandon SD. Impact of a preventative intervention for perinatal depression on mood regulation, social support, and coping. Archives of Womens Mental Health. 2013;16:211-218.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal or postnatal **Baseline symptoms:** Baseline BDI mean 14.5 (mild depression range) **N (number randomised):** 61 **Mean age (years):** 23 **Inclusion criteria:** i) pregnant women or women with a child less than 6 months of age who were enrolled in one of three Baltimore City home visiting programs; ii) women with elevated depressive symptoms (CES-D=>16) and/or a lifetime depressive episode **Exclusion criteria:** i) women currently exhibiting a depressive episode
Interventions	**Experimental intervention** **Name:** Mothers and Babies (MB) CBT-informed psychoeducation group and standard home visiting **Description:** Women received standard home visiting and the Mothers and Babies (MB) CBT group which is a manualized intervention developed by Munoz et al. (2001). Six sessions divided into three two-session modules that map onto core CBT concepts: pleasant activities, thoughts, and contact with others. Each session contains didactic instruction on core content, as well as activities and group discussion. Reinforcement cards were developed for home visitors that summarized key points of each group session and the personal projects given to participants at the end of each session **Format:** Group **Group size:** 6-9 **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Licenced social worker or clincial psychologist **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Women received standard home visiting services plus information on perinatal depression **Format:** Individual

	Group size: N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 6 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (MMS/SCID); Depression mean scores (BDI-II); Drop-out **Outcomes not used:** Data cannot be extracted from MENDELSON2013
Study design	Randomised controlled trial (RCT)
Source of funding	Grant (UL1 RR025005) from the National Center for Research Resources (NCRR) at the National Institutes of Health, as part of a consortium of Clinical and Translational Science Awards (CTSA)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 3. High risk of selective reporting bias as data cannot be extracted from MENDELSON2013
Notes	None

1.11.64 TIMPANO2011

Study ID	TIMPANO2011
Bibliographic reference	Timpano KR, Abramowitz JS, Mahaffey BL, Mitchell MA, Schmidt NB. Efficacy of a prevention program for postpartum obsessive-compulsive symptoms. Journal of Psychiatric Research. 2011;45:1511-1517.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** Sub-threshold symptoms of OCD: Baseline OBQ: 169.9 (SD 23.97) **N (number randomised):** 71 **Mean age (years):** 27.3 **Inclusion criteria:** i) identified as psychologically vulnerable to OCD, defined by a score of 139 or greater (1.25 SD above the community mean) on the Obsessive Beliefs Questionnaire, ii) age 18-65; iii) married or living with a partner; iv) expecting their first child **Exclusion criteria:** i) met DSM-IV criteria (determined using the SCID) for past or current OCD, psychotic disorders, bipolar disorder, and/or current alcohol/substance abuse or dependence
Interventions	**Experimental intervention** **Name:** CBT-informed psychoeducation + Traditional childbirth education (CBE) **Description:** The basic childbirth education (CBE) programme consisted of 6

	weekly 1.5 hour group meetings and covered a range of topics, including the stages of labour, newborn characteristics, and birthing techniques. At the conclusion of each weekly CBE topic, a 30 minute CBT session was added. The intervention was derived from the cognitive-behavioral model of OCD (Rachman, 1997, 1998) and included: (class 1) education about postpartum anxiety and OCS; (class 2) education about the cognitive model of emotion and how OCS fit in this model; (classes 3 & 4) instruction in cognitive restructuring of dysfunctional "obsessive" beliefs; (class 5) instruction in using behavioral experiments and exposure techniques; and (class 6) review and wrap-up. **Format:** Group **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Trained study personnel (including a psychology graduate student) + registered nurse certified in CBE **Control intervention** **Name:** Enhanced Treatment as usual **Description:** The basic childbirth education (CBE) programme consisted of 6 weekly 1.5 hour group meetings and covered a range of topics, including the stages of labour, newborn characteristics, and birthing techniques. At the conclusion of each weekly CBE topic, a 30 minute psychoeducation session was added. The psychoeducation session focused on general anxiety and the specific anxiety disorders, and provided participants with a brief overview of symptoms, prevalence data, and associated demographics for the DSM anxiety disorders, and short videos telling the perinatal stories of several couples. **Format:** Group **Group size:** Not reported **Sessions:** 6 **Frequency (number of doses per week):** 1 **Duration (weeks):** 6 **Provider:** Trained study personnel (including a psychology graduate student) + registered nurse certified in CBE
Outcomes	**Outcomes used:** Drop-out; Mean OCD symptoms (YBOCS); Obsessions mean score (YBOCS); Compulsions mean score (YBOCS) **Outcomes not used:** Data not reported for EPDS, OBQ, SCID and PTBC
Study design	Randomised controlled trial (RCT)
Source of funding	International Obsessive Compulsive Disorder Foundation
Limitations	1. Risk of selection bias is unclear/unknown due to an unclear randomisation method and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. High risk of selective reporting bias as data not reported for EPDS, OBQ, SCID and PTBC
Notes	Data requested, and author response pending, for: Means and standard deviations for all outcomes measured at all time points. Intent-to-treat analyses.

1.11.65 VANDOESUM2008/KERSTENALVAREZ2010

Study ID	VANDOESUM2008/KERSTENALVAREZ2010
Bibliographic reference	Van Doesum KTM, Riksen-Walraven JM, Hosman CMH, Hoefnagels C. A randomized controlled trial of a home-visiting intervention aimed at preventing relationship problems in depressed mothers and their infants. Child Development. 2008;79:547–561. Kersten-Alvarez LE, Hosman CMH, Riksen-Walraven JM, van Doesum KTM, Hoefnagels C. Long-term effects of a home-visiting intervention for depressed mothers and their infants. Journal of child psychology and psychiatry, and allied disciplines. 2010;51:1160-1170.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** Netherlands
Participants	**Timing:** Postnatal **Baseline symptoms:** 95% DSM-IV major depressive episode or dysthymia assessed using MINI, 5% BDI>14. Baseline BDI Mean: 23.6 (SD 8.6) **N (number randomised):** 85 **Mean age (years):** 30 **Inclusion criteria:** i) met DSM– IV criteria for a major depressive episode or dysthymia (95%) assessed using MINI and/or BDI score >14 (5%); ii) were sufficiently fluent in Dutch; iii) were receiving concurrent outpatient treatment for their depression by a qualified local therapist or psychiatrist; iv) infant up to 12 months **Exclusion criteria:** i) comorbid psychotic disorder, bipolar disorder and/or substance dependence
Interventions	**Experimental intervention** **Name:** Mother–baby intervention **Description:** During each home visit, the home visitor monitored and videotaped mother and child during everyday activities, such as bathing or feeding the baby. Subsequently, while watching the tapes together, the home visitor discussed the interactions with the mother, or if present, both parents (discussion was based on analysis of videotaped interactions by multidisciplinary team). The mother was encouraged to expand her range of appropriate communicative behaviors, using the videotapes to show her when to respond to the baby's eye contact, movements, or sounds. In addition to video feedback, one or more of the following four techniques was used, according to individual need: moelling; cognitive restructuring; practical pedagogical support; baby massage. **Format:** Individual **Group size:** N/A **Sessions:** 8-10 **Frequency (number of doses per week):** 0.6 **Duration (weeks):** 15 **Provider:** Home visitors (qualified prevention specialists) affiliated with one of the regional Community Mental Health Centers, all with a master's degree in psychology or social psychiatry and graduate or postgraduate training in prevention or health education

	Control intervention **Name:** Enhanced Treatment as usual **Description:** A minimal intervention involving three telephone calls, during which the mothers were supported with practical parenting advice. The therapists were instructed not to focus on the actual mother – child interaction but to restrict their support to general information about childrearing skills. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 0.2 **Duration (weeks):** 15 **Provider:** Child therapist
Outcomes	**Outcomes used:** Depression mean scores (BDI); Mother-infant attachment (EAS); Child attachment security (AQS); Infant socioemotional functioning (ITSEA); Child self-esteem (Puppet interview); Child ego resiliency (California Child Q-Set); Infant cognitive development (PPVT-R); Child prosocial behaviour (PSBQ); School adjustment (SRS); Child behaviour problems (CBCL/1.5-5); Drop-out **Outcomes not used:** Partner conflict; Stressful life events; Teacher-rated outcomes not extracted as N in each group not reported
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the Netherlands Organization for Health Research and Development (ZonMw), the Foundation for Children's Welfare Stamps Netherlands (SKN), and the Community Mental Health Center, RIAGG IJsselland, the Netherlands
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS)
Notes	Protocol registered: ISRCTN83523136

1.11.66 VIETEN2008

Study ID	VIETEN2008
Bibliographic reference	Vieten C, Astin J. Effects of a mindfulness-based intervention during pregnancy on prenatal stress and mood: results of a pilot study. Archives of Womens Mental Health. 2008;11:67-74.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** 31% of sample CES-D>16. Baseline CES-D mean: 16.8 (SD 5.5) **N (number randomised):** 34 **Mean age (years):** 33.9 **Inclusion criteria:** i) pregnant women 12-30 weeks gestation at the start of the

	intervention; ii) able to speak and read English; iii) had mood concerns (answered affirmatively to the question ''Have you had a history of mood concerns for which you sought some form of treatment, such as psychotherapy, counseling, or medication?'') **Exclusion criteria:** i) women with a history of mental disorders that had a psychotic, dissociative, hallucinatory, or delusional component; ii) an inability to attend each of the classes or participate in the assessments
Interventions	**Experimental intervention** **Name:** Mindfulness ('Mindful Motherhood') training **Description:** The Mindful Motherhood intervention consisted of three components: mindfulness of thoughts and feelings through breath awareness and contemplation; mindfulness of the body through guided meditation and yoga; psychological concepts of mindfulness such as acceptance and cultivation of an 'observing self'. The intervention included education, discussion and exercises. Participants were given weekly reading and guided meditation CD (3x20 min) which they were encouraged to use daily. Pregnancy-specific modifications to mindfulness training included: inclusion of awareness of the developing fetus and belly during the body scan meditation; use of explanatory examples and exercises having to do with pregnancy and early parenting such as mindfulness regarding pain or sleep issues during pregnancy, anxiety about labour, or dealing with a difficult-to-console infant; greater inclusion of walking and moving mindfulness practices and forms of mindful movement that have been tailored for pregnant women such as prenatal yoga **Format:** Group **Group size:** 12-20 **Sessions:** 7 **Frequency (number of doses per week):** 1 **Duration (weeks):** 8 **Provider:** Clinical psychologist and prenatal yoga instructor **Control intervention** **Name:** Waitlist **Description:** Waitlist **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 5 **Provider:** N/A
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (CES-D); Anxiety mean scores (STAI); Parental stress (PSS); Negative affect (PANAS-X); Positive affect (PANAS-X) **Outcomes not used:** Data could not be extracted for 3-month follow-up. Data was not extracted for the Mindful Attention Awareness Scale (MAAS) or for Affect regulation (ARM)
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the Bella Vista Foundation
Limitations	1. Risk of selection bias is unclear/unknown due to an unclear randomisation method and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind

	participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. High risk of selective reporting bias as data could not be extracted for 3-month follow-up
Notes	None

1.11.67 WEIDNER2010

Study ID	WEIDNER2010
Bibliographic reference	Weidner K, Bittner A, Junge-Hoffmeister J, Zimmerman K, Siedentopf F, Richter J, et al. A psychosomatic intervention in pregnant in-patient women with prenatal somatic risks. Journal of psychosomatic obstetrics and gynaecology. 2010;31:188-198.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital **Country:** Germany
Participants	**Timing:** Antenatal **Baseline symptoms:** Baseline HADS Anxiety mean: 9.2 (SD 2.7) **N (number randomised):** 92 **Mean age (years):** 28 **Inclusion criteria:** i) women with high-risk pregnancies or complications during pregnancy admitted to obstetrics and gynaecological ward; ii) elevated scores on the HADS and/or the GBB; iii) >18 years of age; iv) with sufficient knowledge of the German language **Exclusion criteria:** Not reported
Interventions	**Experimental intervention** **Name:** Individualised psychosomatic intervention **Description:** The intervention involved a comprehensive psychosomatic assessment, the assessment of current impairment, of the current psychosocial situation, and of resources and coping mechanisms as well as biographical aspects. Further components of the psychosomatic intervention were crisis intervention, supportive therapy, psychological education and relaxation techniques. The activation of resources and the dialogue about current conflicts were also central aspects of the intervention. **Format:** Individual **Group size:** N/A **Sessions:** 1-5 **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Clinical psychologist or a specialist for psychosomatic medicine and psychotherapy **Control intervention** **Name:** Treatment as usual **Description:** Standard care **Format:** Individual **Group size:** N/A

	Sessions: Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** Not reported **Provider:** Not reported
Outcomes	**Outcomes used:** Anxiety mean scores (HADS); Depression mean scores (HADS); Drop-out **Outcomes not used:** Data not extracted for 'healthy' control group as assignment was not randomised. Data was not extracted for physical complaints (Giessen Subjective Complaints List [GBB-24]) or characteristics of labour (duration of pregnancy, delivery, pain during labour and birth, duration of labour, complications during birth)
Study design	Randomised controlled trial (RCT)
Source of funding	Not reported
Limitations	1. Risk of selection bias is unclear/unknown due to unconcealed allocation 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.68 WICKBERG1996

Study ID	WICKBERG1996
Bibliographic reference	Wickberg B, Hwang CP. Counselling of postnatal depression: a controlled study on a population-based Swedish sample. Journal of Affective Disorders. 1996;39:209-216.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Home **Country:** Sweden
Participants	**Timing:** Postnatal **Baseline symptoms:** Major depression at first interview: 31/41 (76%) **N (number randomised):** 41 **Mean age (years):** 28.4 **Inclusion criteria:** i) score over 12 on the EPDS at 2/3 months postpartum; ii) score 10 or over on the MADRS **Exclusion criteria:** i) already referred to a psychologist/psychiatrist; ii) difficulties with Swedish language
Interventions	**Experimental intervention** **Name:** Listening/counselling visits **Description:** Non-judgemental, empathic, supportive listening. The focus was on the mother rather than the infant **Format:** Individual **Group size:** N/A **Sessions:** 6

	Frequency (number of doses per week): 1 **Duration (weeks):** 6 **Provider:** Child health nurse **Control intervention** **Name:** Treatment as usual **Description:** Possibility of visiting child health clinic whenever needed **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 6 **Provider:** Child health nurse
Outcomes	**Outcomes used:** Depression diagnosis (assessed using Montgomery-Asberg Depression Rating Scale [MADRS] and diagnosed according to DSM-III-R criteria for major depression); Wellbeing (interview); Drop-out; EoC qualitative data (extracted elsewhere) **Outcomes not used:** Data could not be extracted for mean MADRS scores as no sds reported. Dropout is also not possible to extract as the timing of drop-out (pre- versus post-randomisation) and group allocation is unclear
Study design	Randomised controlled trial (RCT)
Source of funding	First of May Flower Annual Campaign and the Foundation of Wilhelm and Martina Lundgren
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method and insufficient detail with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of bias associated with the analysis method as paper reports available case and not possible to compute ITT (WCS) 4. High risk of selective reporting bias as data could not be extracted for mean MADRS scores as no sds reported. Dropout is also not possible to extract as the timing of drop-out (pre- versus post-randomisation) and group allocation is unclear
Notes	Data previously requested from author. No reponse

1.11.69 WIGGINS2005

Study ID	WIGGINS2005
Bibliographic reference	Wiggins M, Oakley A, Roberts I, Turner H, Rajan L, Austerberry H, et al. Postnatal support for mothers living in disadvantaged inner city areas: a randomised control trial. Journal of Epidemiology and Community Health. 2005;59:288-295.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Home **Country:** UK
Participants	**Timing:** Postnatal

	Baseline symptoms: EPDS mean (SD) at baseline = 8.9 (5.4) **N (number randomised):** 731 **Mean age (years):** 29.6 **Inclusion criteria:** i) gave birth in the first nine months of 1999; ii) living in deprived enumeration district **Exclusion criteria:** i) babies had died/became seriously ill/were placed in foster care
Interventions	**Experimental intervention** **Name:** Support health visitor **Description:** The support health visitors' primary focus was on the woman rather than her child, listening to her requests and responding to her needs rather than addressing a predetermined agenda. The SHVs also provided practical support and information on request **Format:** Individual **Group size:** N/A **Sessions:** 10 **Frequency (number of doses per week):** 0.25 **Duration (weeks):** 52 **Provider:** Health visitor **Control intervention** **Name:** Treatment as usual **Description:** One postnatal home visit when the baby was 10–15 days old and clinic support thereafter; subsequent home visits were not routinely made, except for women deemed to be at risk. The community group support (CGS) intervention entailed being assigned to one of eight community groups that offered services for mothers with children less than 5 years in the study area. The groups offered a combination of servuces: drop-in sessions, home visiting, and/or telephone support. However, uptake in this intervention arm was so low (19%) that this group was essentially a second TAU arm and data was therefore combined across the control and CGS arms. **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 52 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression symptomatology (EPDS/GHQ=>12); Developmental concerns about infant (self-assessed); Maternal and infant health service utilisation (self-assessed); Prevention of abuse or neglect (self-assessed); Infant feeding (self-assessed); Drop-out **Outcomes not used:** Data cannot be extracted for social support (Duke UNC Functional Social Support Scale [DUFSS]) as Ns not reported; Maternal smoking; Maternal health (self assessed); Introduction of solid foods before 16 weeks (self assessed)
Study design	Randomised controlled trial (RCT)
Source of funding	Health Technology Assessment Programme of the NHS R& D programme and by the Camden and Islington Health Authority
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of selective reporting bias as data could not be extracted for continuous measures as N not reported

Notes	None

1.11.70 WIKLUND2010

Study ID	WIKLUND2010
Bibliographic reference	Wiklund I, Mohlkert P, Edman G. Evaluation of a brief cognitive intervention in patients with signs of postnatal depression: a randomized controlled trial. Acta Obstetricia et Gynecologica Scandinavica.2010;89:1100-1104.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Not reported **Country:** Sweden
Participants	**Timing:** Postnatal **Baseline symptoms:** Baseline EPDS levels: 15.2 (SD 2.8). NB: Statistically significant group difference in baseline EPDS: 16.9 (3.9) in intervention group and 13.6 (1.93) in control group **N (number randomised):** 67 **Mean age (years):** Not reported **Inclusion criteria:** i) women with healthy newborns, who had an instrumental delivery or an emergency cesarean section; ii) women who scored >12 on EPDS **Exclusion criteria:** i) women who needed psychiatric inpatient care
Interventions	**Experimental intervention** **Name:** Brief individual cognitive behavioral counseling **Description:** Individual cognitive behavioral counseling, focusing on the prevention and management of stress and low mood. A functional analysis based on situation, behavior and consequences of the patients' behavior was conducted. The treatment was thereafter based and focused on behavioral strategies. The participants were, depending on their problem, encouraged to do home tasks such as reading selected literature, daily breathing and relaxation exercises, and thinking about positive things each week. The purpose of these tasks was to help the women with accepting of what had happened during labor and also adapting to their role as mothers. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 1 **Duration (weeks):** 3 **Provider:** Midwife **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Women in the control condition were offered one debirefing session with a midwife or an obstetrician **Format:** Individual **Group size:** N/A **Sessions:** 1 **Frequency (number of doses per week):** 1 **Duration (weeks):** Single session

	Provider: Obstetrician or midwife
Outcomes	**Outcomes used:** Depression symptomatology (EPDS > 10) **Outcomes not used:** Mean EPDS (mean and SD not reported in paper)
Study design	Randomised controlled trial (RCT)
Source of funding	Praktikertjänst AB
Limitations	1. High risk of selection bias due to unclear randomisation method anf allocation concealment and statistically significant group difference in baseline EPDS (16.9 in intervention group and 13.6 in control group) 2. High risk of performance bias as it was not possible to blind participants or personnel 3. High risk of selective reporting bias as data could not be extracted for mean EPDS scores
Notes	Data requested, and author response pending, for: SDs for continous measures

1.11.71 ZELKOWITZ2008/2011/FEELEY2012

Study ID	ZELKOWITZ2008/2011/FEELEY2012
Bibliographic reference	Zelkowitz P, Feeley N, Shrier I, Stremler R, Westreich R, Dunkley D, et al. The cues and care trial: a randomized controlled trial of an intervention to reduce maternal anxiety and improve developmental outcomes in very low birthweight infants. Neonatal Intensive Care. 2008;22:31-36. Zelkowitz P, Feeley N, Shrier I, Stremler R, Westreich R, Dunkley D, et al. The cues and care randomized controlled trial of a neonatal intensive care unit intervention: effects on maternal psychological distress and mother-infant interaction. Journal of Developmental and Behavioral Pediatrics. 2011;32:591-599. Feeley N, Zelkowitz P, Shrier I, Stremler R, Westreich R, Dunkley D, et al. Follow-up of the cues and care trial: mother and infant outcomes at 6 months. Journal of Early Intervention. 2012;34:65-81.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or blinded outcome assessment **Setting:** Hospital and home **Country:** Canada
Participants	**Timing:** Postnatal **Baseline symptoms:** Baseline scores in clinical range: Depression (EPDS=>12): 66%; PTSD: 50%; Anxiety (>40 on STAI State): 54%. Baseline EPDS mean=14.0 (SD 3.8). Baseline STAI mean=47.2 (SD 8.9). Baseline PPQ mean=5.5 (SD 2.0) **N (number randomised):** 121 **Mean age (years):** 30.9 **Inclusion criteria:** i) singleton births; ii) birth weight <1500 g; iii) mothers able to speak and read either English or French; iv) living within a 90-minute radius of the hospital **Exclusion criteria:** i) multiple births; ii) highly unstable infant medical condition such as a Grade IV cerebral hemorrhage; iii) major congenital anomaly; iv) infant likely to be transferred or discharged in 4 weeks; v) infant

	hospitalized in a room with the infant of a mother previously recruited into the study (to avoid exchange of information about the experimental program); vi) infant not in mother's care after discharge
Interventions	**Experimental intervention** **Name:** Cues Program **Description:** The Cues intervention teaches mothers to attend to their own physiological, cognitive, and emotional cues that signal anxiety and worry, and to use cognitive-behavioural strategies to reduce distress. Mothers are also taught to understand infant cues and to respond sensitively to those cues. The experimental "Cues" intervention consists of 6 sessions to teach mothers to: 1) read their own cues and recognize signs of anxiety/distress, 2) utilize various strategies to reduce their distress, including muscle relaxation, imagery, and cognitive reframing, 3) read their infant's communication cues, and 4) respond sensitively to infant cues and distress. In the first two sessions, the intervener explains the relationship between thoughts, feelings, and behaviour, and teaches mothers how to identify negative automatic thoughts. Participants acquire skills that help them to relax and to counteract maladaptive thought patterns. The next two sessions focus on understanding the behaviour of VLBW infants, identifying infant states cues and learning how to interact sensitively with the infant. The fifth session is devoted to mother-infant interaction during feeding. Each teaching session lasts 60 – 90 minutes. There is also a telephone follow-up call, to review the techniques that have been taught and to maintain contact with participant mothers. The intervention employs empirically-based techniques from the domains of cognitive-behaviour therapy and parent sensitivity training. **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 1.5 **Duration (weeks):** Not reported **Provider:** A nurse, a psychologist, or a graduate student in these disciplines **Control intervention** **Name:** Enhanced Treatment as usual **Description:** Care mothers were given general information about infant care, such as sleep position and crib safety. Both groups continued to receive the usual medical, nursing, and other care provided at the 2 study sites and were provided with the same pamphlets containing information about infant care **Format:** Individual **Group size:** N/A **Sessions:** 6 **Frequency (number of doses per week):** 1.5 **Duration (weeks):** Not reported **Provider:** Care intervener
Outcomes	**Outcomes used:** Depression symptomatology (EPDS=>12); PTSD symptomatology (PPQ scores in clinical range); Anxiety symptomatology (STAI State>40); Anxiety mean scores (STAI State); PTSD mean scores (PPQ); Parental stress (PSS; maternal role restriction); Maternal sensitivity (GRS); Maternal intrusiveness (GRS); Overall mother-infant interaction (GRS); Infant positive engagement (GRS); Infant cognitive and physical development (Bayley MDI); Experience of care (satisfaction with intervention and therapeutic alliance); Infant service utilization **Outcomes not used:** Adjusted data not extracted as inconsistent with the data

	analysis approach used for other studies. Data not extracted for maternal remote behaviour and maternal depressive behaviour, or infant liveliness or infant fretfulness subscales of the GRS, or for knowledge of intervention. Data not used for parental stress about infant
Study design	Randomised controlled trial (RCT)
Source of funding	Canadian Institutes of Health Research grant MCT 79216
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 3. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.72 ZLOTNICK2001

Study ID	ZLOTNICK2001
Bibliographic reference	Zlotnick C, Johnson SL, Miller IW, Pearlstein T, Howard M. Postpartum depression in women receiving public assistance: pilot study of an interpersonal-therapy-oriented group intervention. American Journal of Psychiatry. 2001;158:638-640.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or unclear blinding of outcome assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** 57% BDI>10. Baseline BDI mean: 11.06 (SD 6.84; mild depression range) **N (number randomised):** 37 **Mean age (years):** 23.4 **Inclusion criteria:** i) pregnant women receiving public assistance who were at 20-33 weeks gestation and who were attending a prenatal clinic at a general hospital in the Northeast; ii) had at least one predictor of postpartum depression (previous history, mild to moderate levels of depressive symptoms in antenatal period, poor social support, or a life stressor within the last 6 months) **Exclusion criteria:** i) participants who met criteria for current major depression as assessed by the SCID
Interventions	**Experimental intervention** **Name:** Survival Skills for New Moms **Description:** The intervention, Survival Skills for New Moms involved four weekly group sessions. The first session consisted of a rationale for the program and psychoeducation on "baby blues" and postpartum depression. The second session focused on identifying role transitions, changes associated with role transitions, and goals for successfully managing role transitions, with an emphasis on transition to motherhood. The third session was concerned

	with setting goals, developing supports, and identifying potential interpersonal conflicts, especially once the baby was born. The fourth session taught skills for resolving interpersonal conflicts and reviewed the main themes of the intervention. Handouts based on the material presented in each session were given as well as session-related homework assignments. **Format:** Group **Group size:** 4-6 **Sessions:** 4 **Frequency (number of doses per week):** 1 **Duration (weeks):** 4 **Provider:** Not reported **Control intervention** **Name:** Treatment as usual **Description:** Standard care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4 **Provider:** Not reported
Outcomes	**Outcomes used:** Drop-out; Depression diagnosis (SCID); Depression mean score (BDI) **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from the Klingenstein Third Generation Foundation and a grant from Brown University, Department of Psychiatry and Human Behavior
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind participants or personnel 3. Risk of detection bias is unclear for depression diagnosis (SCID) as blinding of outcome assessor was unclear 4. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 5. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.73 ZLOTNICK2006

Study ID	ZLOTNICK2006
Bibliographic reference	Zlotnick C, Miller IW, Pearlstein T, Howard M, Sweeney P. A preventive intervention for pregnant women on public assistance at risk for postpartum depression. American Journal of Psychiatry. 2006;163:1443-1445.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report or unclear blinding of outcome

	assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Baseline mean BDI = 15.6 (SD 5.1) **N (number randomised):** 99 **Mean age (years):** 22.4 **Inclusion criteria:** i) 23-32 weeks' gestation ii) on public assistance iii) attended a prenatal medical clinic ion Providence R.I; iii) score of 27 on 17-item risk survey (Cooper) **Exclusion criteria:** i) receiving mental health treatment/met criteria for a recurrent depressive disorder or substance use disorder
Interventions	**Experimental intervention** **Name:** The ROSE Program **Description:** ROSE programme which is aimed at improving the close interpersonal relationships and change expectations of pregnant women at risk of postnatal depression. Other intervention aims included building and using social support networks, and mastering role transition to motherhood. The content of the four group sessions was as follows: psychoeducation on "baby blues" and postpartum depression; identifying role transitions, changes associated with role transitions, and goals for successfully managing role transitions, with an emphasis on transition to motherhood; setting goals, developing supports, and identifying potential interpersonal conflicts, especially once the baby was born; skills for resolving interpersonal conflicts. The postnatal individual booster session aimed to reinforce the skills learned in the group sessions and to address any current or anticipated mood changes associated with interpersonal difficulties now that the baby has arrived **Format:** Group **Group size:** 3 **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 4 **Provider:** Nurses who had received intensive training and supervision **Control intervention** **Name:** Treatment as usual **Description:** Standard antenatal care **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (LIFE); Mean depression scores (BDI); Functional impairment (LIFE-RIFT); Drop-out **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	Grant from NIMH
Limitations	1. Risk of selection bias is unclear/unknown due to unclear randomisation method and insufficient detail reported with regards to allocation concealment 2. High risk of performance bias as it was not possible to blind

	participants or personnel 3. Risk of detection bias is unclear for depression diagnosis (LIFE) as blinding of outcome assessor was unclear 4. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 5. Risk of selective reporting bias is unclear/unknown
Notes	None

1.11.74 ZLOTNICK2011

Study ID	ZLOTNICK2011
Bibliographic reference	Zlotnick C, Capezza NM, Parker D. An interpersonally based intervention for low-income pregnant women with intimate partner violence: a pilot study. Archives of Women's Mental Health. 2011;14:55-65.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Unclear blinding of outcome assessment **Setting:** Not reported **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Baseline EPDS: 7.9 **N (number randomised):** 54 **Mean age (years):** 23.8 **Inclusion criteria:** i) pregnant women between 18 and 40 years of age; ii) screened positive for recent (past year) IPV, based on their CTS2 responses **Exclusion criteria:** i) met diagnosis for current affective disorders, PTSD, and substance use as determined by the relevant modules of the DSM-IV (assessed using SCID-NP)
Interventions	**Experimental intervention** **Name:** IPT-based intervention **Description:** The intervention was based on the principles of Interpersonal Psychotherapy (IPT), and was aimed at helping participants to improve and change their expectations about their significant interpersonal relationships, assist in building or improving social support networks, and master their role transition to motherhood. The first session focused on topics that included a rationale for the program, review of the course outline, evaluation of healthy relationships, types of interpersonal disputes, and abusive relationships. Topics for session 2 included stress management skills, consequences of abuse, cycle of abuse, and making a safety plan. Topics for session 3 included emotional risks of abuse—signs and symptoms of "baby blues," and postpartum depression, PTSD and substance use, and the management of role transitions with an emphasis on transition to motherhood and self-care. Topics for session 4 included the development of a support system, techniques for asking for support, resolving interpersonal conflicts, and goal-setting. **Format:** Individual **Group size:** N/A **Sessions:** 3 **Frequency (number of doses per week):** 1

	Duration (weeks): 4 **Provider:** Not reported **Control intervention** **Name:** Treatment as usual **Description:** Usual medical care provided for pregnant women at their clinic as well as the educational material and a listing of resources for IPV **Format:** Individual **Group size:** N/A **Sessions:** Not reported **Frequency (number of doses per week):** Not reported **Duration (weeks):** 4 **Provider:** Not reported
Outcomes	**Outcomes used:** Depression diagnosis (LIFE); PTSD diagnosis (LIFE); Depression mean score (PSR); PTSD mean score (PSR) **Outcomes not used:** Data cannot be extracted for the EPDS or Davidson Trauma Scale as Ns not reported in table. Data was not used for the Revised Conflict Tactic Scale (CTS2)
Study design	Randomised controlled trial (RCT)
Source of funding	National Institute of Mental Health (R34 MH075013-01)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Risk of detection bias is unclear as blinding of outcome assessor/s was unclear 3. Risk of bias associated with the analysis method is unclear as paper reports available case and although ITT (WCS) computed where possible, this was not possible for all outcome measures 4. High risk of selective reporting bias as data cannot be extracted for the EPDS or Davidson Trauma Scale as Ns not reported in table
Notes	Data requested, and author response pending, for: Information on the number of participants at each follow up point

1.12PSYCHOSOCIAL INTERVENTIONS: TREATMENT – EXCLUDED STUDIES

Study	Reason for exclusion
Ammerman RT, Putnam FW, Stevens J, Bosse NR, Short JA, Bodley AL, et al. An open trial of in-home CBT for depressed mothers in home visitation. Maternal and Child Health Journal. 2011;15:1333-1341.	Group allocation was not randomised
Araya R, Roja G, Fritsch R, Gaete J, Rojas M, Simon G, et al. Treating depression in primary care in low-income women in Santiago, Chile: a randomised controlled trial. The Lancet. 2003;361:995-1000.	Outside scope (organisation of care)
Clark R, Tluczek A, Brown R. A mother-infant therapy group model for postpartum depression. Infant Mental Health Journal. 2008;29:514-536.	Group allocation was not randomised
Danaher BG, Milgrom J, Seeley JR, Stuart S, Schembri C, Tyler MS, et al. MomMoodBooster web-based intervention for postpartum depression: feasibility trial results. Journal of Medical Internet Research. 2013;15:e242.	Group allocation was not randomised
Duggan AK, Berlin LJ, Cassidy J, Burrell L, Tandon SD. Examing maternal depression and attachment insecurity as moderators of the impacts of home visiting for at-risk mothers and infants. Journal of Consulting and Clinical Psychology. 2009;77:788-799.	Data cannot be extracted
Field T, Diego M, Delgado J, Medina L. Yoga and social support reduce prenatal depression, anxiety and cortisol. Journal of Bodywork and Movement Therapies. 2013;17:397-403.	Data cannot be extracted
Forman DR, O'Hara MW, Stuart S, Gorman LL, Larsen KE, Coy KC. Effective treatment for postpartum depression is not sufficient to improve the developing mother-child relationship. Development and Psychopathology. 2007;19:585-602.	Data cannot be extracted (number of participants in each arm for outcomes not reported)
Gjerdingen D, Crow S, McGovern P, Miner M, Center B. Stepped care treatment of postpartum depression: impact on treatment, health, and work outcomes. Journal of the American Board of Family Medicine. 2009;22:473-482.	Outside scope (organisation of care)
Goodman JH, Guarino A, Chenausky K, Klein L, Prager J, Petersen R, et al. CALM Pregnancy: results of a pilot study of mindfulness-based cognitive therapy for perinatal anxiety. Arch Womens Ment Health. 2014; DOI 10.1007/s00737-013-0402-7.	No control group
Ho S-M, Heh S-S, Jevitt CM, Huang L-H, Fu Y-Y, Wang L-L. Effectiveness of a discharge education program in reducing the severity of postpartum depression. A randomized controlled evaluation study. Patient Education and Counseling. 2009;77:68-71.	Group allocation was not randomised (paper states "The woman with the earliest date of childbirth was assigned to the intervention group and then the next to the control group")
Hou Y, Hu P, Zhang Y, Lu Q, Wang D, Yin L, et al. Cognitive behavioral therapy in combination with systemic family therapy improves mild to moderate postpartum depression. Revista Brasileira de Psiquiatria. 2014;36:47–52.	Group allocation was not randomised
McKee MD, Zayas LH, Fletcher J, Boyd RC, Nam SH. Results of an intervention to reduce perinatal depression among low-income minority women in community primary care. Journal of Social Service Research. 2006;32:63-81.	Mental health outcomes could not be extracted
Misri S, Reebye P, Corral M, Milis L. The use of paroxetine and cognitive-behavioral therapy in postpartum depression and anxiety: a randomized	Paper not available electonically and inter-

controlled trial. Journal of Clinical Psychiatry. 2004;65:1236-1241.	library loan pending
Puckering C, McIntosh E, Hickey A, Longford J. Mellow Babies: a group intervention for infants and mothers experiencing postnatal depression. Counselling Psychology Review. 2010;25:28-38.	Data cannot be extracted
Rahman A, Sikander S, Malik A, Ahmed I, Tomenson B, Creed F. Effective treatment of perinatal depression for women in debt and lacking financial empowerment in a low-income country. British Journal of Psychiatry. 2012;201:451-457.	Outcomes not relevant (moderators of treatment effects in RAHMAN2008)
Richter J, Bittner A, Petrowski K, Junge-Hoffmeister J, Bergmann S, Joraschky P, et al. Effects of an early intervention on perceived stress and diurnal cortisol in pregnant women with elevated stress, anxiety, and depressive symptomatology. Journal of Psychosomatic Obstetrics and Gynecology. 2012;33:162-170.	No mental health outcome reported
Rojas G, Fritsch R, Solis J, Jadresic E, Castillo C, Gonzalez M, et al. Treatment of postnatal depression in low-income mothers in primary-care clinics in Santiago, Chile: a randomised controlled trial. The Lancet. 2007;370:1629-1637.	Outside scope (organisation of care)
Ross R, Sawatphanit W, Suwansujarid T, Stidham AW, Drew BL, Creswell JW. The effect of telephone support on depressive symptoms among HIV-infected pregnant women in Thailand: an embedded mixed methods study. Journal of the Association of Nurses in AIDS Care. 2013;24:e13-e24.	Group allocation was not randomised
Shaw RJ, St John N, Lilo EA, Jo B, Benitz W, Stevenson DK, et al. Prevention of traumatic stress in mothers with preterm infants: a randomized controlled trial. Pediatrics. 2013;132:e886.	Data cannot be extracted
Tezel A, Gözüm S. Comparison of effects of nursing care to problem solving training on levels of depressive symptoms in post partum women. Patient Education and Counseling. 2006;63:64-73.	Group allocation was not randomised

1.13 PSYCHOSOCIAL INTERVENTIONS: ALCOHOL OR SUBSTANCE MISUSE – INCLUDED STUDIES

1.13.1 STADE2009B

Study ID	STADE2009B
Bibliographic reference	Stade BC, Bailey C, Dzendoletas D, Sgro M, Dowswell T, Bennett D. Psychological and/or educational interventions for reducing alcohol consumption in pregnant women and women planning pregnancy. Cochrane Database of Systematic Reviews. 2009b; Issue 2: CD004228.
Study design	Systematic review
Objectives	To determine the effectiveness of psychological and educational interventions to reduce alcohol consumption during pregnancy in pregnant women or women planning pregnancy
Search methods	Searched the Cochrane Pregnancy and Childbirth Group's Trials Register (August 2008), CENTRAL (The Cochrane Library 2007, Issue 4), MEDLINE (1966 to November 2007), EMBASE (1980 to November 2007), CINAHL (1982 to November 2007), Counsel.Lit (1980 to November 2007), PsycLIT (1974 to November 2007) and PsycINFO (1967 to November 2007) and checked cited references from retrieved articles
Selection criteria	Randomized controlled trials examining the effectiveness of psychological and educational interventions for reducing consumption of alcohol among pregnant women, or women planning for pregnancy
Included studies	K=4; N=715 o Chang et al. (1999, 2000) o Handmaker et al. (1999a) o O'Connor & Whaley (2007) o Reynolds et al. (1995) Awaiting assessment: Chang et al. (2005, 2006)
Excluded studies	K=17 (Aalto et al., 2000; Belizan et al., 1995; Calabro et al., 1996; Eisen et al., 2000; Eustace, 2000; Floyd et al., 2007; Fox et al., 1987; Grant et al., 2005; Handmaker et al., 1999b; Hankin & Sokol, 2002; Larsson, 1983; Manwell et al., 2000; Meberg et al., 1986; Palinkas et al., 1996; Reading et al., 1982; Rosett et al., 1983; Scott & Anderson, 1990)
Analyses	Analysis 1.1: Comparison 1-Brief alcohol reduction intervention versus alcohol assessment only; Outcome 1-Women who were abstinent following the intervention. Analysis 1.2: Comparison 1-Brief alcohol reduction intervention versus alcohol assessment only; Outcome 2-Women who remained abstinent throughout the study. Analysis 1.3: Comparison 1-Brief alcohol reduction intervention versus alcohol assessment only; Outcome 3-Number of antenatal alcohol drinking episodes. Analysis 2.1: Comparison 2-Brief cognitive behavioural intervention versus usual advice; Outcome 1-Number abstaining from alcohol at follow up. Analysis 2.2: Comparison 2-Brief cognitive behavioural intervention versus usual advice; Outcome 2-Average drinks per month (post-intervention).
Risk of bias of included studies	Random sequence generation: Low risk of bias in Chang et al. (1999, 2000); Unclear risk of bias in Handmaker et al. (1999a), O'Connor & Whaley (2007)

	and Reynolds et al. (1995). Allocation concealment: Unclear risk of bias in all studies Blinding of participants and personnel: High risk of bias in all studies Blinding of outcome assessment: Unclear risk of bias in Chang et al. (1999, 2000), Handmaker et al. (1999a) and O'Connor & Whaley (2007); High risk of bias in Reynolds et al. (1995). Incomplete outcome data: Low risk of bias in Chang et al. (1999, 2000) and Reynolds et al. (1995); Unclear risk of bias in Handmaker et al. (1999a); High risk of bias in O'Connor & Whaley (2007). Selective reporting: Unclear risk of bias in all studies. Other bias: Unclear risk of bias in all studies.
Notes	None

1.13.2 TERPLAN2007

Study ID	TERPLAN2007
Bibliographic reference	Terplan M, Lui S. Psychosocial interventions for pregnant women in outpatient illicit drug treatment programs compared to other interventions. Cochrane Database of Systematic Reviews; 2007; Issue 4: CD006037.
Study design	Systematic review
Objectives	To evaluate the effectiveness of psychosocial interventions in pregnant women enrolled in illicit drug treatment programs on birth and neonatal outcomes, on attendance and retention in treatment, as well as on maternal and neonatal drug abstinence
Search methods	Searched the Cochrane Drugs and Alcohol Group's trial register (May 2006), the Cochrane Central Register of Trials (Central- The Cochrane Library, Issue 3, 2005); MEDLINE (1.1996-8.2006); EMBASE (1.1996-8.2006); CINAHL (1.1982-8.2006), and reference lists of articles
Selection criteria	Randomised studies comparing any psychosocial intervention versus pharmacological interventions or placebo or non-intervention or another psychosocial intervention for treating illicit drug use in pregnancy
Included studies	K=9; N=
Excluded studies	
Analyses	
Risk of bias of included studies	
Notes	

1.14 PHARMACOLOGICAL INTERVENTIONS: PREVENTION (NO RISK FACTORS) – INCLUDED STUDIES

1.14.1 HARRISONHOHNER2001

Study ID	HARRISONHOHNER2001
Bibliographic reference	Harrison-Horner J, Coste S, Dorato V, Curet LB, McCarron D, Hatton D. Prenatal calcium supplementation and postpartum depression: an ancillary study to a randomised trial of calcium for prevention of preeclampsia. Archives of Women's Mental Health. 2001;3:141-6. Levine RJ, Hauth JC, Curet LB, Sibai BM, Catalano PM, Morris CD. Trial of calcium to prevent preeclampsia. The New England Journal of Medicine. 1997; 337: 69-76
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** NR **Setting:** Clinic-primary **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** NR **N (number randomised):** 374 **Mean age (years):** 22 **Risk factor/s:** N/A **Inclusion criteria:** i) ability to read English; ii) completion of the CPEP study protocol; ii) and delivery of an infant without serious health problems; willing participants mailed the EPDS to complete and return. **Exclusion criteria:** i) Inability to read English; ii) infant with serious health problems; iii) taking medication; iv) obstetric conditions; v) pre-existing diseases (eg. renal); vi) frequent use of calcium supplements; vii) <75% compliant on single-blind compliance test.
Interventions	**Experimental intervention** **Name:** Calcium **Description:** Elemental calcium (Calcium carbonate tablets) **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses):** Mean dose 2000 mg – Taken in split dose (morning and evening meals) **Duration (weeks):** 11-21 weeks, through to delivery **Provider:** NR **Control intervention** **Name:** Placebo **Description:** Tablets identical to calcium tablets **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency:** Taken in split dose (morning and evening meals) **Duration (weeks):** 11-21 weeks, through to delivery **Provider:** NR

Outcomes	**Outcomes used:** From Harrisonhohner paper: EPDS> = 14, EPDS (mean) **Outcomes not used:** From Levine paper: Pregnancy-associated hypertension; Pregnancy-associated proteinuria; preeclampsia; infant weight at birth; Urolithiasis From Harrisonhohner: Norbeck's modification of Sarason's Life Events Survey; calcitonin, parathyroid hormone, calcium and vitamin D
Study design	Randomised controlled trial (RCT)
Source of funding	Supported by a grant from SmithKline Beecham Consumer Healthcare.
Limitations	1. High risk of attrition bias (large drop-out)
Notes	Follow-up study to an RCT, only participants who had completed RCT were considered for inclusion in the study Data request: Mean and SD for 6 week EPDS data. No reply from author

1.14.2 LLORENTE2003

Study ID	LLORENTE2003
Bibliographic reference	Llorente AM, Jensen CL, Voigt RG, Fraley MPH, Berretta LMS, Heird WC. Effect of maternal docosahexaenoic acid supplementation on postpartum depression and information processing. American Journal of Obstetrics and Gynecology. 2003;188:1348-53
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Unclear (for SCID diagnosis), other outcomes self-report **Setting:** Clinic-primary **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** NR **N (number randomised):** 138 **Mean age (years):** 31 **Risk factor/s:** N/A **Inclusion criteria:** Women who are breastfeeding **Exclusion criteria:** NR
Interventions	**Experimental intervention** **Name:** Omega-3 **Description:** Docosahexaenoic acid (derived triglyceride capsules) **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses):** 200 mg DHA/day **Duration (weeks):** 17 **Provider:** NR **Control intervention** **Name:** Placebo **Description:** Capsules identical to DHA capsules **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses):** 200 mg/day idential placebo

	Duration (weeks): 17 **Provider:** NR
Outcomes	**Outcomes used:** BDI (mean), EPDS (mean), SCID-CV; leaving study early for any reason **Outcomes not used:** BDI >=19 – N's not clearly reported BDI > = 9 – N's not clearly reported, Plasma phospholipid fatty acid patterns, laboratory measure of information processing
Study design	Randomised controlled trial (RCT)
Source of funding	Federal funds from US department of Agriculture
Limitations	1. High risk of attrition bias 2. Unclear randomisation method, and blinding of outcomes assessor
Notes	

1.14.3 MAKRIDES2010

Study ID	MAKRIDES2010
Bibliographic reference	Makrides M, Gibson RA, McPhee AJ, Yelland L, Quinlivan J, Ryan P. Effect of DHA supplementation during pregnancy on maternal depression and neurodevelopment of young children: a randomized controlled trial. JAMA: The Journal of the American Medical Association. 2010;304:1675-1683.
Methods	**Blinding of participants:** Yes **Blinding of personnel: Yes** **Blinding of outcome assessment:** **Setting:** Clinic-primary **Country:** Australia
Participants	**Timing:** Antenatal **Baseline symptoms:** NR **N (number randomised):** 2399 **Mean age (years):** 29 **Risk factor/s:** NR **Inclusion criteria:** i) Women with singleton pregnancies; ii) at less than 21 weeks' gestation **Exclusion criteria:** i) If they were already taking a prenatal supplement with DHA; ii) their fetus had a known major
Interventions	**Experimental intervention** **Name:** Omega-3 **Description:** Women allocated to the DHA group were asked to consume three 500-mg/d capsules of DHA-rich fish oil concentrate, providing 800 mg/d of DHA and 100 mg/d of eicosapentaenoic acid (EPA, 20:5n-3; Incromega 500 TG, Croda Chemicals, East Yorkshire, England). All capsules were similar in size, shape, and color and donated by Efamol, Surrey, England **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses):** Daily: three 500-mg/d capsules of DHA-rich fish oil concentrate, providing 800 mg/d of DHA and 100 mg/d of eicosapentaenoic acid **Duration (weeks):** study entry until birth of their child **Provider:** NR

	Control intervention **Name: Placebo** **Description:** Women in the control group were asked to take three 500-mg/d vegetable oil capsules without DHA. The vegetable oil capsules contained a blend of 3 nongenetically modified oils (rapeseed, sunflower, and palm) in equal proportions **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** Daily: three 500-mg/d vegetable oil capsules without DHA **Duration (weeks):** study entry until birth of their child **Provider:** NR
Outcomes	**Outcomes used:** EPDS >=12; Bayley scale of infant and toddler development (for pre-term children and a randomly selected sample of children) – means & categorical data **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	Grant 349301 from the Australian National Health and Medical Research Council
Limitations	
Notes	Protocol registered: ACTRN12605000569606

1.14.4 MOKHBER2011

Study ID	MOKHBER2011
Bibliographic reference	Mokhber N, Namjoo M, Tara F, Boskabadi H, Rayman MP, Ghayour-Mobarhan M. Effect of supplementation with selenium on postpartum depression: A randomized double-blind placebo-controlled trial. Journal of Maternal-Fetal and Neonatal Medicine. 2011;24:104-8.
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** **Setting:** Clinic-primary **Country:** Iran
Participants	**Timing:** Antenatal **Baseline symptoms:** NR **N (number randomised):** 166 **Mean age (years):** 22 **Risk factor/s:** NR **Inclusion criteria:** primigravid women of gestational age up to 12 weeks with a live fetus, and with no serious physical or mental disease and no indications for terminating the pregnancy **Exclusion criteria:** the use of any drugs, but not routine supplements of folic acid and ferrous sulfate, and the occurrence of any severe disease or stressful life events according to the Holmes and Rahe stress scale.
Interventions	**Experimental intervention** **Name:** Selenium **Description:** Selenium tablets

	Format: Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** 100 mg of selenium per day until delivery **Duration (weeks):** from the first trimester of pregnancy until delivery-approximately 26 months **Provider:** NR **Control intervention** **Name:** Placebo **Description**: Matching yeast tablets **Format:** Individual **Group size: N/A** **Sessions: NR** **Frequency (number of doses):** daily **Duration (weeks):** from the first trimester of pregnancy until delivery-approximately 26 months **Provider:** NR
Outcomes	**Outcomes used:** EPDS Serum selenium concentrations (for compliance outcome) **Outcomes not used:** Attachment Subscale of the Social Provisions Scale (SPS-Attachment)
Study design	Randomised controlled trial (RCT)
Source of funding	Financially supported by the Research Council of the Mashhad University of Medical Sciences
Limitations	
Notes	

1.15 PHARMACOLOGICAL INTERVENTIONS: PREVENTION (NO RISK FACTORS) – EXCLUDED STUDIES

Study	Reason for exclusion
N/A	N/A

1.16 PHARMACOLOGICAL INTERVENTIONS: PREVENTION (RISK FACTORS) – INCLUDED STUDIES

1.16.1 HARRIS2002

Study ID	HARRIS2002
Bibliographic reference	Harris B, Oretti R, Lazarus J, Parkes A, John R, Richards C et al. Randomised trial of thyroxine to prevent postnatal depression in thyroid-antibody-positive women. The British Journal of Psychiatry. 2002;180:327-30.
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Clinic-primary **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** 100% Thyroid-positive by vaious endocrinology assessments. % EPDS >13: treatment group: 18.3%; placebo group 15%. RDC diagnosis: treatment group: 17.4%; placebo group 20.1% **N (number randomised):** 446 **Mean age (years):** 29 **Risk factor/s:** 100% Thyroid-positive **Inclusion criteria:** i) Thyroid antibody positive women (associated with postpartum depression) **Exclusion criteria:** i) At screening: existing thyroid disease; ii) premature delivery
Interventions	**Experimental intervention** **Name:** Thyroxine **Description:** Tablet supply of thyroxine **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Tablet supply (daily dose). Mean dose 100 mg **Duration (weeks):** 19.5 **Provider:** NR **Control intervention** **Name:** Placebo **Description:** Tablet supply of placebo **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** Tablet supply (daily dose). Mean dose 100 mg **Duration (weeks):** 19.5 **Provider:** NR
Outcomes	**Outcomes used:** Outcome at 24 weeks only extracted for analysis (endpoint); N's not compliant; RDC(Research Diagnostic Criteria); any depression diagnosis; RDC major depression (definite & probable combined); EPDS >=13; Compliance **Outcomes not used:** Mid-intervention data
Study design	Randomised controlled trial (RCT)

Source of funding	Dunhill Trust
Limitations	1. High risk of selection bias 2. High risk of detection bias
Notes	

1.16.2 LAWRIE1998B

Study ID	LAWRIE1998B
Bibliographic reference	Lawrie TA, Hofmeyr GJ, De Jager M, Berk M, Paiker J, Viljoen E. A double-blind randomised placebo controlled trial of postnatal norethisterone enanthate: the effect of postnatal depression and serum hormones. British Journal of Obstetrics and Gynaecology. 1998;105:1082-90
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Hospital **Country:** South Africa
Participants	**Timing:** Postnatal **Baseline symptoms:** MADRS hormones (6.2), placebo (6.4); EPDS hormones (13.3) placebo (12.6) **N (number randomised):** 180 **Mean age (years):** 32 **Risk factor/s:** Psychosocial risk factors; Low income urban population **Inclusion criteria:** NR **Exclusion criteria:** i) < 19 years at initial recruitment; ii) planning to use hormonal contraception; iii) current antidepressany medication/ psychotherapy
Interventions	**Experimental intervention** **Name:** Noresthisterone enanthate **Description:** Noresthisterone enant hate (synthetic progestogen). Via intramuscular injection over 2 mins to prevent guessing of contents (different viscosities of placebo and test solution) **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Single dose within 48 hours of delivery. Mean dose 200 mg **Duration (weeks):** NR **Provider:** Researcher **Control intervention** **Name:** Placebo **Description:** Normal saline solution via intramuscular injection over 2 mins to prevent guessing of contents (different viscosities of placebo and test solution) **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Single dose within 48 hours of delivery **Duration (weeks):** NR **Provider:** Researcher

Outcomes	**Outcomes used:** EPDS > 11; EPDS (mean) **Outcomes not used:** MADRS >9; MADRS >18; MADRS (mean)
Study design	Randomised controlled trial (RCT)
Source of funding	Research grants from Schering (Pty) Ltd, the Iris Ellen Hodges Trust of the University of the Witwatersrand, the South African Medical Research Council and the South African Institute for Medical Research supported this study
Limitations	1.
Notes	

1.17PHARMACOLOGICAL INTERVENTIONS: PREVENTION (RISK FACTORS) – EXCLUDED STUDIES

Study	Reason for exclusion
N/A	N/A

1.18 PHARMACOLOGIAL INTERVENTIONS (PROPHYLAXIS) – INCLUDED STUDIES

1.18.1 WISNER2001

Study ID	WISNER2001
Bibliographic reference	Wisner KL, Perel JM, Peindl KS, Hanusa BH, Findling RL. Rapport D. Prevention of recurrent postpartum depression: a randomized clinical trial. Journal of Clinical Psychiatry. 2001;62:82-86.
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** **Setting:** Hospital **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** **N (number randomised):** 56 **Mean age (years):** NR **Risk factor/s:** Past history of depression **Inclusion criteria:** i) <=35 weeks' gestation; ii) aged 21-45; iii) at least one past episode of PPMD with onset of symptoms withing the first 3 months after a live birth; iv) at least one past episode of PPMD must have begun within 5 years prior to study enrollment; v) subjects must have been nondepressed since the conception of the index pregnancy. **Exclusion criteria:** i) exposed to an antidepressant after the first trimester of pregnancy; ii) met criteria for any other Axis I diagnosis (except generalized anxiety disorder or panic disorder) or antisocial or borderline personality disorder; iii) past epsodes of psychosis or bipolar disorder; iv) women who chose to continue psychotherapy or use otehr psychotropic medications
Interventions	**Experimental intervention** **Name:** Antidepressants (Nortriptyline) **Description:** 83ng/mL Nortriptyline **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** For the first postpartum week, the dose was increased daily as follows: 20, 30, 40, 50, 60, and 70 mg/day and continued at 75 mg/day through day 21. The serum drug level from day 14 was used **Duration (weeks):** 20 **Provider:** Nurse **Control intervention** **Name:** Placebo **Description:** Placebo tablets **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** Same as the active intervention **Duration (weeks):** 20 **Provider:** Nurse
Outcomes	**Outcomes used:** Recurrance, leaving the study early due to adverse events,

	side effects **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH
Limitations	1. High risk of performance bias
Notes	

1.18.1WISNER2004B

Study ID	WISNER2004B
Bibliographic reference	Wisner KL, Perel JM, Peindl KS, Hanusa BH, Piontek CM et al. Prevention of postpartum depression: a pilot randomized clinical trial. The American Journal of Psychiatry. 2004b;161:1290-92.
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** **Setting:** Hospital **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** **N (number randomised):** 25 **Mean age (years):** 32 **Risk factor/s:** Past history of depression **Inclusion criteria:** The subjects were pregnant with gestations of 35 weeks or less, age 21–45 years, and healthy with normal results from thyroid studies and a complete blood count. Each woman had had at least one episode of postpartum-onset major depression that fit the DSM-IV criteria for major depression within 5 years of enrollment. The subjects were not depressed during the index pregnancy. **Exclusion criteria:** Women who chose to continue psychotherapy or use psychotropic medications after the first trimester were ineligible. Women who met the criteria for any other axis I diagnosis (except generalized anxiety or panic disorder) or for antisocial or borderline personality disorder and those who had psychosis or bipolar disorder were excluded.
Interventions	**Experimental intervention** **Name:** SSRIs (Sertraline) **Description:** A dose reduction to 25 mg/day for 4 days was recommended by the nonblind monitoring team. Thereafter, the dose was increased to 50 mg/day through week 4, then to 75 mg/day during weeks 5–17. At study week 17 the dose was tapered across 3 weeks, and treatment was discontinued at week 20. **Format:** Individual **Group size: N/A** **Sessions:** NR **Frequency (number of doses):** Daily **Duration (weeks):** 17 **Provider:** NR **Control intervention**

	Name: Placebo **Description:** NR **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Daily **Duration (weeks):** 17 **Provider:** NR
Outcomes	**Outcomes used:** Recurrance, Side effects, leaving the study early **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH
Limitations	
Notes	

1.19PHARMACOLOGIAL INTERVENTIONS (PROPHYLAXIS) – EXCLUDED STUDIES

Study	Reason for exclusion
Einarson A, Selby P, Koren G. Abrupt discontinuation of psychotropic drugs during pregnancy: fear of teratogenic risk and impact of counselling. Journal of Psychiatry and Neuroscience. 2000; 26:44-48	No control
Cohen LS, Sichel DA, Robertson LM., et al. Postpartum prophylaxis for women with bipolar disorder. American Journal of Psychiatry. 1995;152:1641-1645	No control
Cohen LS, Altshuler LL, Harlow BL, et al. Relapse of major depression during pregnancy in women who maintain or discontinue antidepressant treatment. The Journal of the American Medical Association. 2006; 295:499-507	No control
Malek AP. Olanzapine in pregnancy. Annals of Pharmacotherapy. 2001;35:1294-1295	No control
Sharma V., et al. Olanzapine in the prevention of postpartum psychosis and mood episodes in bipolar disorder. Bipolar Disorders. 2006; 8:400-404	Not an RCT
Wisner KL. Prevention of recurrent postpartum major depression. Hospital and Community Psychiatry. 1994;45:1191-1196	No control
Wisner KL, Hanusa BH, Peindl KS, et al. Prevention of postpartum episodes in women with bipolar disorder. Biological Psychiatry. 2004;56:592-596	No control

1.20 PHARMACOLOGICAL INTERVENTIONS: TREATMENT – INCLUDED STUDIES

1.20.1 APPLEBY1997

Study ID	APPLEBY1997
Bibliographic reference	Appleby L, Warner R, Whitton A, Faragher B. A controlled study of fluoxetine and cognitive-behavioural counselling in the treatment of postnatal depression. British Medical Journal. 1997;314:932- 936
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** NR **Setting:** Clinic-primary **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS Fluoxetine group = 17.2, Placebo group=16.9 **N (number randomised):** 87 **Mean age (years):** 25 **Risk factor/s:** N/A **Inclusion criteria:** i) Subjects were women found by screening in an urban health district to be depressed 6-8 weeks after childbirth; ii) scored >12 on the revised clinical interview schedule, the threshold for significant psychiatric morbidity, and who satisfied research diagnostic criteria16 for major or minor depressive disorder **Exclusion criteria:** i) English not adequate; ii) living outside district; iii) EPDS score <10; iv) chronic depression (>2 years) or resistant depression; v) current drug/alcohol misuse; vi) severe illness requiring close monitoring /hospital admission; vii) breastfeeding.
Interventions	**Experimental intervention** **Name:** SSRIs (fluoxetine) + counselling (either single session or six sessions) **Description: NR** **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** NR **Provider:** NR **Control intervention** **Name:** Placebo + counselling (either single session or six sessions) **Description:** NR **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** NR **Provider:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	

Limitations	1.
Notes	Emailed author for dichotomous data. Reply: no additional data A four armed trial. Data combinedfor the two SSRI groups (either counseling single session, or six sessions) compared with the two placebo groups (either counceling single session, or six sessions)

1.20.2 BLOCH2012

Study ID	BLOCH2012
Bibliographic reference	Bloch M, Meiboom H, Lorberblatt M, Bluvstein I, Aharonov I, Schreiber S. The effect of sertraline add-on to brief dynamic psychotherapy for the treatment of postpartum depression: A randomized, double-blind, placebo-controlled study. Journal of Clinical Psychiatry. 2012;73:235-241
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Clinic-primary **Country:** Israel
Participants	**Timing:** Postnatal **Baseline symptoms:** MADRS = 20 **N (number randomised):** 42 **Mean age (years):** NR **Risk factor/s:** N/A **Inclusion criteria**: i) 18-45 years; ii) criteria met during the screen and baseline visits for current major depressive disorder (DSM-IV-TR); iii) onset of the depressive episode starting within 2 months of parturition **Exclusion criteria:** i) MADRS score >=30; ii) suicidal ideation, psychotic symptoms, bipolar disorder, length of current episode longer than 6 months, current treatment with antidepressants, 2 failed adequate trials of antidepressants; and major physical illness or alcoholism or drug use
Interventions	**Experimental intervention** **Name:** SSRI (sertraline) + Brief dynamic therapy **Description:** 12 sessions of focused brief dynamic psychotherapy concurrently with 8-week sertraline, followed by a 4-week open phase **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** 25 mg of sertraline for 1 week, followed by 50 mg for 3 more weeks. After 4 weeks, the psychiatrist was allowed to either continue the same dose or increase the dose to 100 mg for the next 4 weeks. **Duration (weeks):** 8 **Provider:** NR **Control intervention** **Name:** Placebo + Brief dynamic therapy **Description:** 12 sessions of focused brief dynamic psychotherapy concurrently with 8 week Dummy pills, identical in appearance to the active pills **Format:** Individual **Group size:** N/A

	Sessions: NR **Frequency (number of doses):** daily pills **Duration (weeks):** 8 **Provider:** NR
Outcomes	**Outcomes used:** MADRS & EPDS (remission <10 MADRS, <7 EPDS), UKU Side Effects Rating Scale **Outcomes not used:** CGI-I, CGI-S, Mental Health Inventory (MHI)
Study design	Randomised controlled trial (RCT)
Source of funding	
Limitations	1.
Notes	For response- Used the LOCF analysis + additional 2 drop-outs as WCS, could not calculate completer analysis. Used 8 week data (as 12 week from an open phase) Protocol registered: NCT01028482

1.20.3 FREEMAN2008

Study ID	FREEMAN2008
Bibliographic reference	Freeman MP, Davis M, Sinha P, Wisner KL, Hibbeln JR, Gelenberg AJ. Omega-3 fatty acids and supportive psychotherapy for perinatal depression: A randomized placebo-controlled study. Journal of Affective Disorders. 2008;110:142-148
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** NR **Country:** US
Participants	**Timing:** Antenatal and postnatal **Baseline symptoms:** Met criteria for MDD, verified with the Structured Clinical Interview for DSM-IV (SCID) **N (number randomised):** 59 **Mean age (years):** 30 **Risk factor/s:** N/A **Inclusion criteria:** women 18–45years of age who were either pregnant (12–32weeks gestation) or postpartum (within six months of childbirth) and met criteria for MDD, verified with the Structured Clinical Interview for DSM-IV (SCID) (postpartum women must have experienced onset of MDD by 4weeks postpartum), scored ≥ 9 on the Edinburgh Postnatal Depression Scale (EPDS) (Cox et al., 1987), outpatient status, and ability to provide written informed consent. **Exclusion criteria:** previous intolerance to omega-3 fatty acids, current use of antidepressants or anticoagulants, psychosis, diagnosis of bipolar disorder, active substance abuse, or active suicidal ideation.
Interventions	**Experimental intervention** **Name:** Omega 3 (puls supportive psychotherapy) **Description:** 1.1g of EPA and 0.8g of DHA in a total of 4 capsules a day **Format:** Individual **Group size:** N/A **Sessions:** NR

	Frequency (number of doses): 1.1g of EPA and 0.8g of DHA in a total of 4 capsules a day **Duration (weeks):** 8 **Provider:** NR **Control intervention** **Name:** Placebo **Description:** Corn oil with 1% of fish oil added **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 8 **Provider:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	NIMH
Limitations	1. High selective reporting bias: SIGH-ADS and red blood cel count are listed in protocol but not reported. Published paper additionally reports HAM-D scores which are not listed in the protocol
Notes	Protocol registered: NCT00402389

1.20.4 GREGOIRE1996

Study ID	GREGOIRE1996
Bibliographic reference	Gregoire AJ, Kumar R, Everitt B, Henderson AF, Studd JWW. Transdermal oestrogen for treatment of severe postnatal depression. Lancet. 1996;347:930-933
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** **Country:** UK
Participants	**Timing:** Antenatal **Baseline symptoms:** Diagnosis of non-psychotic depression by SADS clinical review **N (number randomised):** 64 **Mean age (years):** 31 **Risk factor/s:** N/A **Inclusion criteria:** i) a score of 14 or more on the EPDS on two occasions 1 month apart; ii) the presence of a major depressive disorder as shown by the RDC and the SADS interview; iii) and an onset of depression within the first 12 weeks post partum; iv) patients had to be no more than 18 months post partum and not breastfeeding at the time of recruitment; v) they had to agree to use non-hormonal contraception during the trial, and written informed consent was obtained frm all participants **Exclusion criteria:** i) <18 months postpartum; ii) EPDS <14; depression onset >12 weeks postpartum; iii) breastfeeding; change in psychotropic medication in previous 6 weeks; iv) hormonal prep. taken since delivery; v) history of

	uterine, cervical or breast disorders; vi) previous evidence of thromboembolic disease.
Interventions	**Experimental intervention** **Name:** Oestradiol patch **Description:** Participants received unmarked 100ug oestradiol patches and were instructed to apply two patches at a time to give a daily dose of about 200ug 17b-oestradiol, and to change them twice each week. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Two patches to give a daily dose **Duration (weeks):** 26 **Provider:** NR **Control intervention** **Name:** Placebo patch **Description:** Participants received similar unmarked 100ug placebo patches and were instructed to apply two patches at a time to give a daily dose of about 200ug 17b-oestradiol, and to change them twice each week. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** Two patches to give a daily dose **Duration (weeks):** 26 **Provider:** NR
Outcomes	**Outcomes used:** EPDS (mean); EPDS >=14; leaving study early **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	Ciba Pharmaceuticals
Limitations	1.
Notes	

1.20.5 HANTSOO2014

Study ID	HANTSOO2014
Bibliographic reference	Hantsoo L, Ward-O'brien D, Czarkowski KA, Gueorguieva, R. Price, LH, Epperson CN. A randomised, placebo-controlled, double-blind trial of sertraline for postpatrum depression. Psychopharmacology. 2014;231:939-948
Methods	**Blinng of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Clinic **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** **N (number randomised):** 38 **Mean age (years):** 31 **Risk factor/s:** N/A **Inclusion criteria:** The women were between ages 18 and 45 years old, and were recruited to a university-based women's mental health clinical and

	research program if they (1) reported depression onset within the first 3 months of delivery, (2) were not taking a psychotropic medication for at least 5 weeks, and (3) had given birth to an infant without serious medical issues within the previous 12 months. The participants were required to have a score of at least 18 and less than 32 on the 19-item HAM-D (Hamilton 1960) and to exhibit symptoms that were at least "moderate" in severity as defined by the severity of illness rating on the CGI scale**.** **Exclusion criteria:** The participants screening positive for thyroid disease were excluded unless their thyroid condition was stable. Other exclusions included a history of drug or alcohol dependence within the last 6 months or positive urine drug test during screening, past or present history of an Axis I psychotic disorder (including bipolar type I), presence of active suicidal ideation, any significant medical conditions or plan to become pregnant, or past failed trial of sertraline.
Interventions	**Experimental intervention** **Name:** SSRIs (Sertraline) **Description:** The study drug was prescribed initially as sertraline 50 mg daily. As tolerated, the dosage was increased by one capsule (50 mg) every 1-2 weks until clinical remission was obtained, with a maximum of four capsuled (200 mg) per day. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** daily **Duration (weeks): 6** **Provider: Pharmacist** **Control intervention** **Name:** Placebo **Description:** The study drug was prescribed initially as pacebo daily. As tolerated, the dosage was increased by one capsule (50 mg) every 1-2 weks until clinical remission was obtained, with a maximum of four capsuled (200 mg) per day. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** daily **Duration (weeks):** 6 **Provider:** Pharmacist
Outcomes	**Outcomes used:** Response, remission, adverse events, leaving the study early **Outcomes not used:** NR
Study design	Randomised controlled trial (RCT)
Source of funding	Pfizer, NIMH and National Institute of Drug Abuse
Limitations	1.
Notes	

1.20.6 MOZURKEWICH2013

Study ID	MOZURKEWICH2013
Bibliographic reference	Mozurkewich EL, Clinton CM, Chilimigras JL, Hamilton S, Allbaugh L, Berman D et al. The Mothers, Omega-3, and Mental Health Study: a double-blind, randomized controlled trial. American Journal of Obstetrics and Gynecology. 2013;208:e1-9
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Prenatal clinic **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** EPDS omega-3=8.1 (5.47), placebo=7.21 (5.21) **N (number randomised):** 126 **Mean age (years):** 30 **Risk factor/s:** N/A **Inclusion criteria:** i) a past history of depression; ii) an EPDS score 9-19 (at risk for depression or mildly depressed); iii) singleton gestation; iv) a maternal age of 18 years or older; v) a gestational age of 12-20 weeks **Exclusion criteria:** i) A history of a bleeding disorder; ii) thrombophilia requiring anticoagulation; iii) multiple gestation; iv) bipolar disorder; v)current major depressive disorder; vi) current substance abuse; vii) lifetime substance dependence; viii) schizophrenia; ix) if they were currently taking omega-3 fatty acid supplements or antidepressant medications; x) if they were eating more than 2 fish meals per week
Interventions	**Experimental intervention** **Name:** Omega-3 (DHA and DHA rish fish oil) **Description:** Either EPA-rich fish oil (ProEPAXtra, Nordic Naturals) contained an approximate 4:1 ratio of EPA to DHA (1060 mg EPA plus 274 mg DHA) or DHA-rich oil (ProDHA, Nordic NatuRrals) contained DHA and EPA in an approximate 4:1 ratio (900 mg DHA plus 180 mg EPA) **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** daily **Duration (weeks):** Unclear **Provider:** NR **Control intervention** **Name:** Placebo **Description:** The placebos were formulated to be identical in appearance to both the EPA- and DHA-rich supplements and contained 98% soybean oil and 1% each of lemon and fish oil **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses):** daily **Duration (weeks):** Unclear **Provider:** NR
Outcomes	**Outcomes used**: BDI, MINI **Outcomes not used:** Infant outcomes ie. Bayley scales

Study design	Randomised controlled trial (RCT)
Source of funding	University of Michigan
Limitations	1.
Notes	Protocol registered: NCT0071197; Protocol lists only the BDI at 6 weeks post-partum as an outcome, however the published paper also reportes diagnoses of depression according to the MINI

1.20.7REES2008

Study ID	REES2008
Bibliographic reference	Rees AM, Austin MP, Parker GB. Omega-3 fatty acids as a treatment for perinatal depression: Randomized double-blind placebo-controlled trial. Australian and New Zealand Journal of Psychiatry. 2008;42:199-205
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Clinic-primary **Country:** Australia
Participants	**Timing:** Antenatal and postntatal **Baseline symptoms:** EPDS omega-3 = 17.3 (2.7), Placebo=16.5 (2.3) **N (number randomised):** 26 **Mean age (years):** 33 **Risk factor/s:** N/A **Inclusion criteria:** i) > 21 years of age; ii) from the third trimester of pregnancy to 6 months postnatal **Exclusion criteria:** i) bipolar disorder; ii) psychosis; iii) drug and alcohol abuse; iv) obsessive compulsive disorder; v) eating disorder or personality disorder; vi) an unstable medical condition, diabetes; vii) receipt of anticoagulants; viii) having a fish allergy
Interventions	**Experimental intervention** **Name:** Omega-3 **Description:** The fish oil soft gelatin capsules and matching placebos were dispensed in identical plastic containers. The fish oil capsules contained 27.3% DHA, 6.9% EPA (total omega-3 fatty acids 35.6%) and 3.3% omega-6 fatty acids. The remainder of the capsule content consisted of monounsaturated fats and a small amount of saturated fat. Vitamin E (80 mg) was added to prevent oxidation of the oil. Peppermint oil was added to all capsules to disguise any fish taste and may also have minimized the gastrointestinal side-effects **Format:** Individual **Group size:** N/A **Sessions:** 6g a day fish oil every two week **Frequency (number of doses):** daily **Duration (weeks):** 6 **Provider:** dispensed by the hospital pharmacy **Control intervention** **Name:** Placebo **Description:** Sunola oil was used to constitute the placebo, which consisted mainly of monounsaturated fatty acids (85%) and a small amount of saturated fat (7%) and polyunsaturated fats (8%). Peppermint oil was added to all

	capsules to disguise any fish taste and may also have minimized the gastrointestinal side-effects **Format:** Individual **Group size:** N/A **Sessions:** 6g placebo every 2 weeks **Frequency (number of doses):** daily **Duration (weeks):** 6 **Provider:** dispensed by the hospital pharmacy
Outcomes	**Outcomes used:** EPDS, dropout, adverse events **Outcomes not used:** HRSD, MADRS,
Study design	Randomised controlled trial (RCT)
Source of funding	Research grants from the NSW Institute of Psychiatry, a Neuroscience Research Grant from Pfizer Australia, an NHMRC Program Grant (222708) and an Infrastructure Grant from the NSW Department of Health.
Limitations	1.
Notes	

1.20.8 SHARP2010

Study ID	SHARP2010
Bibliographic reference	Sharp DJ, Chew-Graham C, Tylee A, Lewis G, Howard L, Anderson I, et al. A pragmatic randomised controlled trial to compare antidepressants with a community-based psychosocial intervention for the treatment of women with postnatal depression: the RESPOND trial. Health Technology Assessment. 2010;14(43):iii-iv, ix-xi, 1-153
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** GP practices **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** Scored ≥ 13 on the baseline EPDS or received an ICD-10 primary diagnosis of depression on the CIS-R **N (number randomised):** 254 **Mean age (years):** 29 **Risk factor/s:** N/A **Inclusion criteria:** i) scored ≥ 13 on the baseline EPDS; ii) received an ICD-10 primary diagnosis of depression on the CIS-R; iii) were proficient in English at a level to complete all research assessments (two women whose first language was not English had some language assistance in completing the assessments and/ or listening visit intervention); iv)their recently delivered baby was less than 26 weeks old **Exclusion criteria:** i) were already taking psychoactive medication or receiving psychological therapy; ii) were actively suicidal
Interventions	**Experimental intervention** **Name:** Antidepressants (mainly SSRIs) **Description:** Women randomised to antidepressants were asked to make an appointment with their own GP as soon as possible, to discuss the prescription of an appropriate antidepressant. Although an SSRI was recommended as a

	first-line treatment, a pragmatic approach was employed whereby the GP and the patient agreed which antidepressant medication should be prescribed. The guidelines advised noting the past response to an SSRI, previous adverse effects of any SSRIs, any concurrent medication and potential interactions, and the profile of the preferred SSRI regarding breastfeeding. The guidelines suggested that women be monitored after 2 weeks to assess side effects, and at 4 weeks to review treatment efficacy, and then every 4 weeks until 28 weeks. GPs were also guided on increasing the dose, changing the antidepressant medication or stopping pharmacotherapy altogether. Information on the antidepressant prescribed and treatment adherence was obtained through women's self-report at all follow-up points, and by recording prescribing information from women's medical notes. **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** NR **Duration (weeks):** 4 **Provider:** GP **Control intervention** **Name:** General supportive care **Description:** Group were placed on a 4-week waiting period (to mimic a clinical waiting list) **Format:** Individual **Group size:** N/A **Sessions:** N/A **Frequency (number of doses per week):** N/A **Duration (weeks):** 4 **Provider:** GP
Outcomes	**Outcomes used:** EPDS >13, EPDS score, drop out **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	NIHR
Limitations	1.
Notes	

1.20.9 SU2008

Study ID	SU2008
Bibliographic reference	Su KP, Huang SY, Chiu TH, Huang KC, Huang CL, Chang HC. Omega-3 fatty acids for major depressive disorder during pregnancy: Results from a randomized, double-blind, placebo-controlled trial. Journal of Clinical Psychiatry. 2008;69:644-651
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** **Setting:** **Country:** Taiwan
Participants	**Timing:** Antenatal **Baseline symptoms:** EPDS omega-3 = 16.8 (3.8), Placebo=17.5 (4.0)

	N (number randomised): 40 **Mean age (years):** 31 **Risk factor/s:** N/A **Inclusion criteria:** Eligible participants were pregnant women, aged 18 to 40 years, with DSM-IV major depressive disorder onset between their 16th week (second trimester) and 32nd week (third trimester) of gestation seen at the Department of Obstetrics during the 24- month study period (June 2004 to June 2006). **Exclusion criteria:** Subjects were excluded if they had a DSM-IV diagnosis of bipolar disorder, psychotic disorder, or substance abuse/dependence or any Axis II diagnosis of borderline or antisocial personality disorder. Participants were required to be free from any psychotropic agents at least 1 month, to have a score of at least 18 on the 21-item Hamilton Rating Scale for Depression (HAM-D) at screening phase, and to have good physical health as determined by medical history, physical examination, blood laboratory results, electrocardiogram, chest radiography, and urinalysis.
Interventions	**Experimental intervention** **Name:** Omega-3 **Description:** After the placebo lead-in phase, participants were randomly assigned (at week 0) to receive 5 identical gelatin capsules per day containing omega-3 fatty acids for 8 weeks. The capsules contained a total daily dosage of omega-3 fatty acid with 2.2g of EPA and 1.2 g of DHA, which were produced from menhaden fish body oil concentrate. The capsules (omega-3 fatty acid and placebo) were vacuum deodorized, amended by blending with orange flavor, and supplemented with tertiary butylhydroquinone, 0.2 mg/g, and tocopherols, 2 mg/g, as antioxidants. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** daily **Duration (weeks):** 8 **Provider:** NR **Control intervention** **Name:** Placebo (olive oil ethyle esters) **Description:** After the placebo lead-in phase, participants were randomly assigned (at week 0) to receive 5 identical gelatin capsules per day containing placebo (olive oil ethyl esters) for 8 weeks. The capsules were vacuum deodorized, amended by blending with orange flavor, and supplemented with tertiary butylhydroquinone, 0.2 mg/g, and tocopherols, 2 mg/g, as antioxidants. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** daily **Duration (weeks):** 8 **Provider:** NR

Outcomes	**Outcomes used:** EPDS, response, remission **Outcomes not used:** HRDS, BDI
Study design	Randomised controlled trial (RCT)
Source of funding	National Science Council, DoH, China Medica University and Hospital (Taiwan)
Limitations	2.
Notes	

1.20.10 WISNER2006

Study ID	WISNER2006
Bibliographic reference	Wisner KL, Hunusa BH, Perel JM, Peindl KS, Piontek CM, Sit DKY et al. Postpartum depression: a randomised trial of sertraline versus nortriptyline. Journal of Clinical Psychopharmacology. 2006;26:353-360
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** Yes **Setting:** Clinic-primary **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** **N (number randomised):** 109 **Mean age (years):** NR **Risk factor/s:** N/A **Inclusion criteria:** Subjects aged 15 to 45 years with major depression with postpartum onset (within 4 weeks of birth according to DSM-IV were eligible. During the trial, additional funding was obtained to include women who had chronic depression (defined as an episode of major depression that began before the index pregnancy); these women were included after the trial began. Mothers had to present for treatment within 3 months of delivery. A 17-item Hamilton Rating Scale for Depression (HRSD) score of 18 or more was required for inclusion. **Exclusion criteria:** Exclusion criteria were the presence of any other Axis I disorder except generalized anxiety disorder or panic disorder, contraindications to TCA treatment, and concurrent psychiatric treatment.
Interventions	**Experimental intervention (1)** **Name:** Sertraline **Description:** All subjects were treated with a fixed-dose strategy. Doses were not titrated to serum level asis usually done for NTP because therapeutic levels for SERT have not been defined, and this approach might offer an advantage to NTP. The dosing began with 25 mg/d of SERT. Because several initial subjects randomized to SERT had moderate to severe headaches, we reduced the initial dose from 50 to 25 mg/d for 2 days. Thereafter, the doses were increased to 50 mg/d SERT and increased until either response or side effects prohibited further dose escalation. The maximum doses were 200 mg/d SERT. **Format:** Individual **Group size:** N/A

	Sessions: NR **Frequency (number of doses per week):** daily **Duration (weeks):** 8 **Provider:** Pharmacist **Experimental intervention (2)** **Name:** Nortriptyline **Description:** All subjects were treated with a fixed-dose strategy. Doses were not titrated to serum level as is usually done for NTP because therapeutic levels for SERT have not been defined, and this approach might offer an advantage to NTP. The dosing began with 10 mg/d of NTP. Thereafter, the doses were increased to 25 mg/d NTP and increased until either response or side effects prohibited further dose escalation. The maximum doses were 150 mg/d NTP. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** daily **Duration (weeks):** 8 **Provider:** NR
Outcomes	**Outcomes used:** remission, reposnse, HRDS, CGI, leaving the study early **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	Pfizer
Limitations	1.
Notes	

1.20.11 YONKERS2008

Study ID	YONKERS2008
Bibliographic reference	Yonkers KA, Lin H, Howell HB, Heath AC, Cohen LS. Pharmacologic treatment of postpartum women with new-onset major depressive disorder: A randomized controlled trial with paroxetine. Journal of Clinical Psychiatry. 2008;69:659-665
Methods	**Blinding of participants:** Yes **Blinding of personnel:** Yes **Blinding of outcome assessment:** **Setting:** **Country:** US
Participants	**Timing:** Postnatal **Baseline symptoms:** **N (number randomised):** 70 **Mean age (years):** 26 **Risk factor/s:** N/A **Inclusion criteria:** at least 16 years of age, met diagnostic criteria for MDD with an onset in the three months post-delivery, were within nine months of delivery at intake and had a score on the 17-item Hamilton Rating Scale for Depression (HRS-D17) 9 of at least 16 at the initial visit. **Exclusion criteria:** Subjects were excluded if they had an onset of MDD prior to delivery, suffered from current (within the last 6 months) alcohol or drug

	abuse or dependence, showed evidence of current psychotic symptoms, had a lifetime diagnosis of schizophrenia, bipolar disorder or schizoaffective disorder, were receiving treatment (pharmacotherapy or psychotherapy) for a psychiatric disorder, had suicidal ideation with intent, were currently pregnant, were unwilling to be randomized to either placebo or active medication or were unable to attend treatment visits at a participating site.
Interventions	**Experimental intervention** **Name:** SSRIs (Paroxetine) **Description:** After randomization, subjects were instructed to take 1 capsule (10 mg of immediate release paroxetine) daily for the first and second week; this was increased to two capsules during the third and fourth weeks of the study unless side effects limited an increase. Further increments to 30 mgs and then 40 mgs were encouraged if improvement was less than 30% compared to baseline by week 4 and week 6, respectively **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** daily **Duration (weeks):** 6 **Provider:** NR **Control intervention** **Name:** Placebo **Description:** After randomization, subjects were instructed to take 1 capsule of similar appearing placebo daily for the first and second week; this was increased to two capsules during the third and fourth weeks of the study unless side effects limited an increase. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** daily **Duration (weeks):** 6 **Provider:** NR
Outcomes	**Outcomes used:** HRDS, GCI, response, remission, compliance, adverse effects, leaving the study early **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	GSK
Limitations	1.
Notes	

1.21 PHARMACOLOGICAL INTERVENTIONS: TREATMENT – EXCLUDED STUDIES

Study	Reason for exclusion
Ahokas A, Kaukoranta J, Wahlbeck K., Estrogen deficiency in severe postpartum depression: su ccessful treatment with sublingual physiologic 17beta-estradiol: a preliminary study. Journal of Clinical Psychiatry. 2001;62:332-336	Open label; no control
Cerutti R, Sichel MP, Perin M, et al. Psychological distress during puerperium: a novel therapeutic approach using Sadenosylmethionine. Current Therapeutic Research. 1993;53:707-717	Insufficient extractable data (incl. no numbers given for treatment versus placebo group)
Cohen LS, Viguera AC, Bouffard SM, et al. Venlafaxine in the treatment of postpartum depression. Journal of Clinical Psychiatry.2001;62:592-596	No control group
Freeman MP, Hibbeln JR, Wisner KL, et al. Randomized dose-ranging pilot trial of omega-3 fatty acids for postpartum depression. Acta Psychiatrica Scandinavica. 2006;113:31-35	Insufficient data provided for extraction no control
Freeman MP, Hibbeln JR, Wisner KL, et al. An open trial of Omega-3 fatty acids for depression in pregnancy. Acta Neuropsychiatrica. 2006;18:21-24	No control group
Misri S, Milis L. Obsessive compulsive disorder in the postpartum: open label trial of quetiapine augmentation. Journal of Clinical Psychopharmacology. 2004;24:624-627	No control group
Nonacs RM, Soares CN, Viguera AC, et al. Bupropion SR for the treatment of postpartum depression: a pilot study. International Journal of Neuropsychopharmacology. 2005;8:445-449	No control group
Suri R, Burt VK., Altshuler LL, et al. Fluvoxamine for postpartum depression. American Journal of Psychiatry. 2001;158:1739-1740	Not an RCT: open label; no control; small sample size of 6
Suri R, Burt VK, Altshuler LL. Nefazodone for the treatment of postpartum depression. Archives of Women's Mental Health. 2005;8:55-56	Not an RCT: brief report of study only (letter to the editor); open label
Van Der Meer YG. Effect of high-dose progesterone in post-partum depression. Journal of Psychosomatic Obstetrics and Gynaecology. 1984;3:67-68	No details of randomisation reported. Insufficient maternal mental health outcomes
Stowe ZN, Casarella J, Landry J., et al. Sertraline in the treatment of women with postpartum major depression. Depression. 1995;3:49-55	No control group

1.22PHARMACOLOGICAL INTERVENTIONS: HARMS

1.23 ANTIDEPRESSANTS – INCLUDED STUDIES

1.23.1BOUCHER2008

Study ID	BOUCHER2008
Bibliographic reference	Boucher N, Bairam A, Beaulac-Baillargeon L. A new look at the neonate's clinical presentation after in utero exposure to antidepressants in late pregnancy. Journal of clinical psychopharmacology. 2008:28;334-339
Systematic review source	Gridoradias et al., 2013A; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Maternal and neonatal hospital charts **Country:** Canada
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 146 **N Exposed:** 73 **N Unexposed:** 73 **Mean age (years):** 29 **Diagnosis:** NR **Inclusion criteria:** retrospective study of neonates exposed and non-exposed to antidepressants in the last 3 weeks of pregnancy was performed. The selected neonates were born between February 2002 and March 2005 in a secondary and tertiary care facilities hospital (2000 births/year). Antidepressant exposed mothers were identified through the hospitals' pharmacy electronic database for prescription of antidepressant drugs **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, paroxtine, sertraline, fluoxetine, fluvoxamine, venlafaxine, amitriptyline, trazodone, mirtazapine **Dosage:** NR
Outcomes	**Outcomes used:** PostnatalAS, respiratory distress, tremors **Outcomes not used:** N/A (only outcomes from systematic reviews were used)
Study design	Cohort
Source of funding	
Limitations	
Notes	Matched for same hospital, gestational age, and date at delivery (no group difference for smoking, alcohol or drugs)

1.23.2CALDERON-MARGALIT2009

Study ID	CALDERON-MARGALIT2009
Bibliographic reference	Calderon-Margalit R, Qiu C, Ornoy A, Siscovick DS, Williams MA. Risk of preterm delivery and other adverse perinatal outcomes in relation to maternal use of psychotropic medications during pregnancy. American Journal of Obstetrics and Gynecology. 2009;201:579.e1-8

Methods	**Prospective/Retrospective:** Prospective **Data collection:** medical files **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 2631 **N Exposed:** 138 **N Unexposed:** 2493 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** Women who were eligible for inclusion in the Omega study were those who initiated prenatal care at _20 weeks of gestation, who were at least 18 years old, who could speak and read English, who planned to carry the pregnancy to term, and who planned to deliver at either 1 of the 2 study hospitals. Participants were interviewed during a prenatal visit at _20 weeks of gestation by trained research personnel who used a structured questionnaire. **Exclusion criteria:** NR
Interventions	**Drug class:** Depression **Drug/s examined:** Paroxetine, Sertraline, Fluoxetine, Fluvoxamine, Citalopram, Escitalopram, Venlafaxine (analysed as all SSRIs) **Dosage:** NR
Outcomes	**Outcomes used:** Preterm delivery **Outcomes not used:** NR
Study design	Cohort
Source of funding	
Limitations	
Notes	

1.23.3 CASPER2003

Study ID	CASPER2003
Bibliographic reference	Casper RC, Fleisher BE, Lee-Ancajas JC, Gilles A, Gaylor E, DeBattista A, et al. Follow-up of children of depressed mothers exposed or not exposed to antidepressant drugs during pregnancy. Journal of Pediatrics. 2003;142:402-8
Systematic review source	Ross et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:** Prospective and retrospective **Data collection:** Interview and questionnaire **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:**NR **Total N:** 44 **N Exposed:** 31 **N Unexposed:** 13 **Mean age (years):** 36 **Diagnosis:** Depression **Inclusion criteria:** Women who were in treatment in the Women's Wellness Clinic or with other clinicians and who met DSM-IV criteria17 for Major Depressive Disorder during pregnancy were invited to participate in the follow-up study

	Exclusion criteria:
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Sertraline, fluoxetine, paroxetine, fluvoxamine **Dosage:** The average daily doses of sertraline, fluoxetine, and paroxetine were 113.2 ± 72.3 mg, 20 ± 11.9 mg, and 17.2 ± 10.1 mg, respectively
Outcomes	**Outcomes used:** Preterm delivery **Outcomes not used:** Child developmental outcomes
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Only used preterm delivery as an outcome from the ROSS2013 systematic review

1.23.4 CHAMBERS1996

Study ID	CHAMBERS1996
Bibliographic reference	Chambers CD, Johnson KA, Dick LM, Felix RJ, Jones KL. Birth outcomes in pregnant women taking fluoxetine. New England Journal of Medicine. 1996;335:1010-15
Systematic review source	Gridoradias et al., 2013A; Gridoradias et al., 2013B; Myles et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone record and medical interview **Country:** Canada, US
Participants	**Trimester of exposure:** All trimesters **Duration of exposure:** NR **Total N:** 390 **N Exposed:** 164 **N Unexposed:** 226 **Mean age (years):** 31 **Diagnosis:**. The primary indication for treatment with fluoxetine was depression (133 women [76.9 percent]); other conditions included anxiety (14 women [8.1 percent]), panic disorder (11 women [6.4 percent]), bipolar disorder (10 women [5.8 percent]), and obsessive–compulsive disorder (7 women [4.0 percent]) **Inclusion criteria:** From 1989 through 1995, the California Teratogen Information Service and Clinical Research Program received approximately 1500 calls requesting information on the potential teratogenic effects of fluoxetine. An estimated one third of these inquiries were made by pregnant women currently taking the drug. Selected 228 of these women for inclusion in the study on the basis of accessibility by telephone and willingness to participate. During this same period, pregnant women who called the program with questions about drugs and procedures not considered teratogenic- including acetaminophen use, dental radiography, and limited alcohol ingestion (1 oz [30 ml] of 100 percent alcohol per week before pregnancy was recognized) — were asked to enroll in the study as a control group. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Fluoxetine

	Dosage: 26.5 mg
Outcomes	**Outcomes used:** Congenital malformations, Major congenital malformations **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.5 COSTEI2002

Study ID	COSTEI2002
Bibliographic reference	Costei AM, Kozer E, Ho T, Ito S, Koren G. Perinatal outcome following third trimester exposure to paroxetine. Archives of Pediatrics and Adolescent Medicine. 2002;156:1129-32
Systematic review source	Gridoradias et al., 2013C
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Interview **Country:** Canada
Participants	**Trimester of exposure:** 3 **Duration of exposure:** Third trimester **Total N:** 109 **N Exposed:** 55 **N Unexposed:** 27 **Mean age (years):** 33 **Diagnosis:**. Depression (565), anxiety (31%), anxiety and depression (13%), panic attacks (9%) **Inclusion criteria:** Exposure to paroxetine throughout the third trimester. Between September 1996 and 1999, followed all pregnant women who called the motherisk program about paroxetine exposure during the third trimester of pregnancy. For each case, a control mother-child pair from the same prospective cohort was chosed and matched for maternal age, gravity, parity, social drug use (alcohol and smoking), and nonteratogenic drug use **Exclusion criteria:** Pregnant women who discontinued paroxetine before the third trimester of those receiving other drugs known to cause withdrawal-type symptoms, such as opiods, benzodiazepines, barbiturates, or heavy use of ethanol
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Paroxetine **Dosage:** Mean: 23 mg (10 mg-60 mg)
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	
Limitations	
Notes	

1.23.6 DAVIS2007

Study ID	DAVIS2007
Bibliographic reference	Davis RL, Rubanowice D, McPhillips H, Raebel MA, Andrade SE, Smith D, et al. Risks of congenital malformations and perinatal events among infants exposed to antidepressant medications during pregnancy. Pharmacoepidemiology and Drug Safety. 2007;16:1086-94
Systematic review source	Gridoradias et al., 2013A, Myles et al., 2013; Wurst et al., 2010; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** health system databases **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** SSRI: 9836, TCA: 49836 **N Exposed:** SSRIs=805, TCAs=167 **N Unexposed:** SSRI comparison = 49031, TCA comparison=49669 **Mean age (years):** NR **Diagnosis:**. NR **Inclusion criteria:** The study population was identified from discharge diagnoses and procedure codes from both community and HMO-owned hospitals.We identified female members older than 15 years of age who were admitted to a hospital between January 1, 1996 and December 31, 2000 for delivery of an infant and were continuously enrolled with prescription drug coverage for 1 year prior to the admission **Exclusion criteria:** infants for whom 30 days of post-delivery follow-up were not available
Interventions	**Drug class:** Antidepressants **Drug/s examined:** SSRIs, TCAs **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, cardiac malformations, respiratory distress **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Stratified by health system, maternal age, birth season

1.23.7 DIAV-CITRIN2008B

Study ID	DIAV-CITRIN2008B
Bibliographic reference	Diav-Citrin O, Shechtman S, Weinbaum D, Wajnberg R, Avgil M, Di Gianantonio E, et al. Paroxetine and fluoxetine in pregnancy: A prospective, multicentre, controlled, observational study. British Journal of Clinical Pharmacology. 2008:66; 695-705
Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:** Prospective **Data collection:** telephone interview or mailed questionnaire to the woman or

	the child's paediatrician **Country:** Israel, Italy, Germany
Participants	**Trimester of exposure:** 1 **Duration of exposure:** median duration of treatment was 224 days (IQR 56–280) in the paroxetine and 240 days (IQR 49–280) in the fluoxetine groups **Total N:** 2276 **N Exposed:** Paroxetine = 463, Fluoxetine = 346 **N Unexposed:** 1467 **Mean age (years):** 32 **Diagnosis:** depression, anxiety, obsessive compulsive disorder, manic depressive disorder, schizoaffective disorder and eating disorder **Inclusion criteria:** pregnant women who contacted the Israeli Teratology Information Service (TIS) (Jerusalem, Israel), Servizio di Informazione Teratologica (Padua, Italy) or Pharmakovigilanz-und Beratungszentrum für Embryonaltoxikologie (Berlin, Germany) with regard to gestational exposure to paroxetine or fluoxetine between the years 1994 and 2002 in Israel and Italy, and between 2002 and 2005 in Germany. The three TISes are members of the European Network of Teratology Information Services, an organization of counselling services with regard to environmental exposure during pregnancy, and use a similar methodology. The exposed groups were compared with a control group of women who contacted one of the three participating centres during pregnancy regarding exposures known not to be teratogenic in similar time frames. The common exposures for which control women contacted the TISes were antibiotics (for example penicillins, cephalosporins), oral contraceptives taken no later than the first 4–5 weeks of pregnancy, low-dose diagnostic irradiation, topical preparations with negligible systemic absorption, paracetamol, hair dye and housecleaning agents, iron supplementation, and thyroxine replacement. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Paroxetine, fluoxetine **Dosage:** The median daily dose [interquartile range (IQR) between the 25–75th percentiles] of paroxetine and fluoxetine was 20 mg (IQR 20–20) and 20 mg (IQR 20–40),respectively.The median duration of treatmentwas 224 days (IQR 56–280) in the paroxetine and 240 days (IQR 49–280) in the fluoxetine groups
Outcomes	**Outcomes used:** Major congenital malformation, congenital malformation, cardiac malformation **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.8 EINARSON2009

Study ID	EINARSON2009
Bibliographic reference	Einarson A, Boskovic R. Use and safety of antipsychotic drugs during pregnancy. Journal of Psychiatric Practice. 2009;15:183-92
Systematic review source	Gridoradias et al., 2013A

Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview, physician report **Country:** Canada
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 1856 **N Exposed:** 928 **N Unexposed:** 928 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** Used data from women who contacted us for the antidepressant exposure and compared them with an equal number of women who were not exposed to antidepressants and who had called Motherisk for information regarding nonteratogenic drugs, such as acetaminophen. To assess the number of major malformations, we only included women who were exposed to the antidepressant during the first trimester. The 2 groups were matched for maternal age, smoking, and alcohol use **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** bupropion, citalopram, escitalopram, fluvoxamine, nefazodone, paroxetine, mirtazepine, fluoxetine, trazodone, venlafaxine, sertaline **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations **Outcomes not used:** NR
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Matched for maternal age, smoking, alcohol use

1.23.9 ELMARROUN2014

Study ID	ELMARROUN2014
Bibliographic reference	El Marroun H, White TJH, Van der Knaap NJF, Homberg JR, Fernandez G, Schoemaker NK et al. Prenatal exposure to selective serotonin reuptake inhibitors and autistic symptoms in young children: population-based study of young children. The British Journal of Psychiatry. 2014;205:95-102.
Systematic review source	Hand search
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Parental report **Country:** Netherlands
Participants	**Trimester of exposure:** At least first trimester **Duration of exposure:** NR **Total N:** 445 **N Exposed:** 69 **N Unexposed:** 376

	Mean age (years): Maternal age at intake 29, child age 6 **Diagnosis:** Depression **Inclusion criteria:** The present study is embedded in an ongoing population-based cohort, the Generation R Study.18 All pregnant women resident in Rotterdam were invited to participate. In total, 8880 mothers were enrolled during pregnancy (delivery from April 2002 to January 2006). The Medical Ethics Committee of the Erasmus Medical Centre, Rotterdam, approved the study. Written informed consent was obtained from all participants. For the present analyses, only children who participated in the pre- and postnatal follow-up (n = 8098) were considered **Exclusion criteria:** if information on maternal SSRI use was unavailable
Interventions	**Drug class:** Antidepressants **Drug/s examined:** SSRIs **Dosage:** NR
Outcomes	**Outcomes used:** Autistic traits, pervasive developmental problems, affective problems **Outcomes not used:** N/A
Study design	Cohort
Source of funding	
Limitations	
Notes	Data used for the exposed to SSRI group compared to the exposed to depression group and not the reference group

1.23.10 FERREIRA2007

Study ID	FERREIRA2007
Bibliographic reference	Ferreira E, Carceller AM, Agogue C, Martin BZ, St-Andre M, Francoeur D, et al. Effects of selective serotonin reuptake inhibitors and venlafaxine during pregnancy in term and preterm neonates. Pediatrics. 2007;119:52-9
Systematic review source	Ross et al., 2013; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Patient charts **Country:** Canada
Participants	**Trimester of exposure:** 3 **Duration of exposure:** 32 months (range: 1–132 months) **Total N:** 166 **N Exposed:** 76 **N Unexposed:** 90 **Mean age (years):** 31 **Diagnosis:** major depression (41%), mixed disorders (26%), other anxiety disorders 16%), generalized anxiety disorders (14%), and unknown (3%) **Inclusion criteria:** The study population included women who delivered at CHU Sainte-Justine between January 1, 2002, and July 31, 2004, and their newborns. We studied 2 groups of women: those taking SSRIs or venlafaxine and a control group. This study was conducted before the Health Canada Advisory in August 2004 regarding the possible association between late exposure to SSRIs during pregnancy and adverse neonatal outcomes. **Exclusion criteria:** Mothers using benzodiazepines, barbiturates, and any other antidepressant on a daily basis during pregnancy or at the time of delivery were excluded from exposed and unexposed groups. Other drugs for chronic diseases were permitted

Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, fluoxetine, fluvoxamine, paroxetine,sertraline venlafaxine (any antiudepressant) **Dosage:**
Outcomes	**Outcomes used: Tremors, PNAS, respiratory distress** **Outcomes not used:** N/A
Study design	Cohort
Source of funding	
Limitations	
Notes	

1.23.11 GALBALLY2009

Study ID	GALBALLY2009
Bibliographic reference	Galbally M, Lewis A, Lum J, Buist A. Serotonin discontinuation syndrome following in utero exposure to antidepressant medication: prospective controlled study. Australian and New Zealand Journal of Psychiatry. 2009;43:846-54
Systematic review source	Gridoradias et al., 2013C
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Questionnaire **Country:** Australia
Participants	**Trimester of exposure:** Through to third trimester **Duration of exposure:** NR **Total N**: 50 **N Exposed:** 23 (complete data available) **N Unexposed**: 27 **Mean age (years):** 32 **Diagnosis:** depression **Inclusion criteria:** The Victorian psychotropic registry recruited 27 women who were treated with an SSRI, serotonin and noradrenaline re-uptake inhibitor (SNRI) or noradrenergic and specific serotonergic antidepressant (NaSSA) for depression during their pregnancy between June 2004 and July 2005. A total of25 ofthese women remained on medication in the third trimester oftheir pregnancies; the period considered relevant to exposure related to discontinuation symptoms.Subjects were recruited at Mercy Hospital for Women, a tertiary obstetric hospital in Melbourne, Australia. A matched control group of 27 pregnant women not taking antidepressants and not depressed at the time oftheir recruitment were recruited prospectively via antenatal appointments at the Mercy Hospital for Women **Exclusion criteria:** Women with substance dependence, inability to provide informed consent, or lack of English proficiency
Interventions	**Drug class:** Antidepressants **Drug/s examined:** All antidepressants [Sertraline (14), venlafaxine (2), fluoxetine (2), citalopram (2), fluvoxamine(1), mianserin (1), mirtazepine (1), paroxetine (1), escitalopram (1)] **Dosage:** Unclear
Outcomes	**Outcomes used:** Tremors, respiratory distress

	Outcomes not used: N/A
Study design	Cohort
Source of funding	Neuroscience Research Grant, Pat and Toni Kinsman Scholarship, Pfizer, Lundbeck and Wyeth
Limitations	
Notes	

1.23.12 KALLEN2004

Study ID	KALLEN2004
Bibliographic reference	Kallen B. Neonate characteristics after maternal use of antidepressants in late pregnancy. Archives of Pediatrics & Adolescent Medicine. 2004;158:312-6
Systematic review source	Check
Methods	**Prospective/Retrospective:** Prospective (prospectively recorded information) **Data collection:** Medical Birth Registry **Country:** Sweden
Participants	**Trimester of exposure:** At least third trimester **Duration of exposure:** NR **Total N:** 583793 **N Exposed:** 997 **N Unexposed:** 582796 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** Data were obtained from the Swedish Medical Birth Registry. Since July 1, 1994, information on maternal drug use during pregnancy has been collected prospectively.12 From July 1, 1995, the records of all women delivered of a neonate Exposed infants were compared with all infants in the registry after adjustment for year of birth, maternal age, parity, and maternal smoking in early pregnancy should contain information on drug use. Children born between July 1, 1995, and December 31, 2001, were selected for study. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Tricyclic drugs (including clomipramine and amitriptyline; SSRIs (including citalopram, paroxetine, fluoxetine and sertraline, and other antidepressants (including venlafaxine). **Dosage:** NR
Outcomes	**Outcomes used:** Respiratory distress **Outcomes not used:** N/A
Study design	Cohort
Source of funding	
Limitations	
Notes	Data analysed for 'any antidepressant' as a class as data not disaggregated for individual drug

1.23.13 KALLEN2007

Study ID	KALLEN2007
Bibliographic reference	Kallen B. Congenital malformations in infants whose mothers reported the use of folic acid in early pregnancy in Sweden. A prospective population study. Congenital Anomalies. 2007;47:119-24
Systematic review source	Gridoradias et al., 2013A
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** The Medical Birth Register **Country:** Sweden
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 880431 **N Exposed:** 6555 **N Unexposed:** 873876 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** Data were available for infants born on July 1, 1995 and later. Drug information is stored as ATC codes (Anatomical Therapeutic Chemical classification system). Drug information was obtained from routine midwife interviews at the first antenatal care center visit (practically all pregnant Swedish women attend the free antenatal care visit system) using a standardized form, which is identical throughout the country **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Paroxetine, fluoxetine, citalopram, sertraline, fluuvoxamine, escitalopram **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, cardiac malformations, spetal defects (ASD and/or VSD), VSD **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Adjusted for year of birth, maternal age, parity, smoking, previous miscarriages

1.23.14 KIELER2012

Study ID	KIELER2012
Bibliographic reference	Kieler H, Artama M, Engeland A, Ericsson O, Furu K, Gissler M, et al. Selective serotonin reuptake inhibitors during pregnancy and risk of persistent pulmonary hypertension in the newborn: Population based cohort study from the five Nordic countries. British Medical Journal. 2012;344:1-9
Systematic review source	Gridoradias et al., 2013B
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** Denmark, Finland, Iceland, Norway, Sweden

Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 1618255 **N Exposed:** 30115 **N Unexposed:** 1588140 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** We identified all singletons born after 231 gestational days (33 weeks) between 1996 and 2007. Only births were included from the years when prescription data were available. Accordingly we included births from: Denmark 1997-2007, Finland 1996-2006, Iceland 2003-7, Norway 2005-7, and Sweden 2006-7. From the registers we obtained information on persistent pulmonary hypertension of the newborn, level of delivery hospital, maternal smoking, body mass index in early pregnancy, year of birth, mode of delivery, gestational age at birth, birth weight, meconium aspiration, and maternal diseases recorded during pregnancy. Maternal diseases included epilepsy, malignancies, rheumatoid arthritis, juvenile arthritis, and arthritis in connection with psoriasis or inflammatory bowel disease, inflammatory bowel disease, systemic lupus erythematosus, and hypertension or pre-eclampsia **Exclusion criteria:** infants ≤33 wks gestation at birth; multiple pregnancy
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Fluoxetine, citalopram, paroxetine, sertraline, fluvoxamine, escitalopram **Dosage:** NR
Outcomes	**Outcomes used:** Persistant pulmonary hypotension **Outcomes not used:** NR
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.15 KORNUM2010

Study ID	KORNUM2010
Bibliographic reference	Kornum JB, Nielsen RB, Pedersen L, Mortensen PB, Norgaard M. Use of selective serotonin-reuptake inhibitors during early pregnancy and risk of congenital malformations: updated analysis. Clinical Epidemiology. 2010;2:29-36
Systematic review source	Gridoradias et al., 2013A; Ross et al., 2013
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** prescription databases and national registry of patients **Country:** Denmark
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 215774 **N Exposed:** 2062 **N Unexposed**: 213712 **Mean age (years):** 30

	Diagnosis: NR **Inclusion criteria**: **a**ll women in the counties who had a live birth after the 20th week of gestation during the periods covered by the prescription registries. The women were identified through the Danish Medical Birth Registry, which contains information on all births in Denmark since January 1973 **Exclusion criteria:** women who used antiepileptics (ATC code N03A) during the first trimester of pregnancy or 90 days before conception or who used antidiabetic drugs (ATC code A10) at any time before conception or during the entire pregnancy.
Interventions	**Drug class:** Antidepressants **Drug/s examined:** paroxetine, fluoxetine, sertraline, citalopram, escitalopram, **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, cardiac malformations, preterm delivery **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Only data for SSRIs used (non-SSRI antidepressant not used as unclear which class these belong to)

1.23.16 KULIN1998

Study ID	KULIN1998
Bibliographic reference	Kulin NA, Pastuszak A, Sage SR, Schick-Boschetto B, Spivey G, Feldkamp M, et al. Pregnancy outcome following maternal use of the new selective serotonin reuptake inhibitors: a prospective controlled multicenter study. Journal of the American Medical Association. 1998;279:609-10
Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013; Ross et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:**Prosepctive **Data collection:** **Country: Canada, US**
Participants	**Trimester of exposure:** 1 **Duration of exposure:** 49 used drug throughout the pregnancy **Total N:** 534 **N Exposed:** 267 (147 Sertraline; 97 paroxetine; 26 fluvoxamine) **N Unexposed:** 267 **Mean age (years):** 31 **Diagnosis:**. Depression **Inclusion criteria:** All women who contacted 1 of 9 participating Teratology Information Service centres regarding exposure to fluvoxamine, paroxetine, and sertraline during the first trimester of pregnancy for depression. The group exposed to SSRIs was matched to controls who were randomly selected from the total group of women counseled and followed by the Motherisk Program after exposure to agents proven to be non-teratogenic (eg. dental x-rays, acetaminophen). **Exclusion criteria:** Women who, in addition to being exposed to a new SSRI,

	were also exposed to a known human teratogen or drugs of uncertain teratogenicicity.
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Sertraline, paroxetine, fluvoxamine **Dosage:** Sertraline 50 mg/d (range 25-250 mg/d); paroxetine 30 mg/d (range 10-60 mg/d); fluvoxamine 50 mg/d (range 25-200 mg/d)
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, spontaneous abortion **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Groups 'matched'- no difference between groups for alcohol or age, parity or previous spontaneous abortion

1.23.17 LAINE2003

Study ID	LAINE2003
Bibliographic reference	Laine K, Heikkinen T, Ekblad U, Kero P. Effects of exposure to selective serotonin reuptake inhibitors during pregnancy on serotonergic symptoms in newborns and cord blood monoamine and prolactin concentrations. Archives of General Psychiatry. 2003;60:720-26
Systematic review source	Ross et al., 2013; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Clinical examination **Country:** Finland
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:**NR **Total N:** 40 **N Exposed:** 20 **N Unexposed:** 20 **Mean age (years):** 33 **Diagnosis:** depression (50%), panic disorder (20%) **Inclusion criteria:** Forty pregnant women were enrolled in the controlled, prospective, follow-up study between January 1, 1997 and August 31, 2000.Patients were referred to the study clinic by primary care physicians. A control group of 20 healthy women who were not taking psychotrophic medication was prospectivly and individually matched for confounding obstetric characteristics at the time of delivery **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, fluoxetine **Dosage:** 20-40 mg/d
Outcomes	**Outcomes used:** Persistant pulmonary hypotension **Outcomes not used:** N/A.
Study design	Cohort
Source of funding	

Limitations	
Notes	Matched for: maternal age, gravidity, parity, gestational age, time and mode of delivery. Only PPHT used as an outcome as found in ROSS2013

1.23.18 LEVINSONCASTIEL2006

Study ID	LEVINSONCASTIEL2006
Bibliographic reference	Levinson-Castiel R, Merlob P, Linder N, Sirota L, Klinger G. Neonatal abstinence syndrome after in utero exposure to selective serotonin reuptake inhibitors in term infants. Archives of Pediatrics and Adolescent Medicine. 2006;160:173-76
Systematic review source	Gridoradias et al., 2013A
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records **Country:** Israel
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** exposure to SSRIs during the entirepregnancy or at least during the third trimester **Total N:** 120 **N Exposed:** 60 **N Unexposed:** 60 **Mean age (years):** 32 **Diagnosis:**. NR **Inclusion criteria:** This cohort study was performed at Rabin Medical Center in Israel, a tertiary care facility housing a neonatology department that cares for approximately 9000 newborns per year. The study was conducted from January 1, 2002, through August 31, 2004, during which 23 254 consecutive births took place. Maternal intake of SSRIs during pregnancy, including fluoxetine, paroxetine hydrochlo-ride, citalopram hydrobromide, sertraline hydrochloride, and the serotonin-noradrenaline reuptake inhibitor venlafaxine hydrochloride, was recorded in each case. All full-term infants who had had prolonged exposure to SSRIs during the entire pregnancy or at least during the third trimester were eligible for the study. The infants were identified from the delivery room records as they arrived at the nursery or from a medical history form completed by all mothers at admittance to the nursery. This form included demographic details; maternal and family illnesses; type, dosage, and duration of treatment with SSRIs or other drugs; and use of recreational drugs, tobacco, or alcohol. A control cohort of infants was similarly identified during the final 2 months of the study and included an equal number of healthy non–SSRI-exposed neonates born to healthy mothers and matched for sex, gestational age (±1 week), birth weight (±100 g), and mode of delivery **Exclusion criteria:** known or probable exposure to other medications, illicit drugs, or alcohol, which could have contributed to a NAS, congenital anomalies or conditions affecting the central nervous system. Infants who were exposed to SSRIs or who met any of the exclusion criteria were excluded from the control cohort. Preterm infants also were excluded owing to the difficulty of assessing the Finnegan score in this population.
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Any SSRI (37 paroxetine; 12 fluoxetine; 8 citalopram; 2

	venlafaxine; 1 sertraline) **Dosage:** paroxetine (dose range, 10-40 mg), fluoxetine (dose range, 20-60 mg), citalopram (dose range, 10-40 mg), venlafaxine (dose range, 37.5-75 mg), sertraline (dose, 25 mg)
Outcomes	**Outcomes used:** Congenital malformations, cardiac malformations, respiratory distress, tremors, PNAS, VSD **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Matched for sex, gestational age, mode of delivery, birthweight (excluded other medications, recreational drugs, alcohol, conditions or congenital anomalies affecting the CNS, preterm infants)

1.23.19 MALM2011

Study ID	MALM2011
Bibliographic reference	Malm H, Artama M, Gissler M, Ritvanen A. Selective serotonin reuptake inhibitors and risk for major congenital anomalies. Obstetrics and Gynecology. 2011;118:111-20
Systematic review source	Myles et al., 2013
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical databases **Country:** Finland
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 635,583 **N Exposed:** Citalopram (2799), fluoxetine (1818), paroxetine (968), sertraline (869), escitalopram (441), fluvoxamine (240) **N Unexposed:** 618727 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** The Medical Birth Register collects data on maternal background and medical history, diagnoses during pregnancy and delivery, and neonatal outcome data up to age 7 days. Data in the register are collected from all maternity hospitals and include all births, including the occasional home births. All neonates are examined at hospital by a pediatrician. All live births and stillbirths with gestational age of 22 weeks or more or birth weight of 500 g or more are included in the register. **Exclusion criteria:**
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, fluoxetine, paroxetine, sertraline, escitalopram, fluvoxamine **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, cardiac malformations, spetal defects, ASD, VSD **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR

Limitations	
Notes	

1.23.20 MASCHI2008

Study ID	MASCHI2008
Bibliographic reference	Maschi S, Clavenna A, Campi R, Schiavetti B, Bernat M, Bonati M. Neonatal outcome following pregnancy exposure to antidepressants: a prospective controlled cohort study. BJOG: An International Journal of Obstetrics and Gynaecology. 2008;115:283-89
Systematic review source	Myles et al., 2013; Wurst et al., 2010; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Drug and Health Information Centre **Country:** Italy
Participants	**Trimester of exposure:** Any timester **Duration of exposure:** NR **Total N:** 1400 **N Exposed:** 200 **N Unexposed:** 1,200 **Mean age (years):** 31 **Diagnosis:** depression (77%), anxiety (25%) and panic attacks (7%) **Inclusion criteria:** Women who called the Drug and Health Information Centre at the 'Mario Negri' Institute22 took antidepressants during pregnancy and delivered live born children between 1995 and 2003 were enrolled as cases. Pregnant women who were counselled at the Centre on the use of non-teratogenic drugs or drugs that do not cause neonatal adverse effects, such as antibiotics or paracetamol, were recruited as a control group. For each case, six controls were randomly selected from the same prospective cohort and matched for maternal age and gravidity **Exclusion criteria:** Women with chronic diseases known to affect the pregnancy outcome (for example diabetes and hypertension) or those receiving other drugs known to cause withdrawal type symptoms, such as opioids, benzodiazepines and barbiturates, were excluded.
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Paroxetine, fluoxetine (combined in analysis), amitriptyline **Dosage:** The daily dosage of paroxetine ranged from 5 to 40 mg (median 20 mg); the daily dosage of fluoxetine ranged from 5 to 60 mg (median 20 mg) and the daily dosage of amitriptyline ranged from 4 to 80 mg (median 20 mg)
Outcomes	**Outcomes used:** congenital malformations, major congenital malformations, preterm delivery, PNAS **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.21 OBERLANDER2006

Study ID	OBERLANDER2006
Bibliographic reference	Oberlander TF, Warburton W, Misri S, Aghajanian J, Hertzman C. Neonatal outcomes after prenatal exposure to selective serotonin reuptake inhibitor antidepressants and maternal depression using population-based linked health data. Archives of General Psychiatry. 2006;63:898-906
Systematic review source	
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Hospital records and registries **Country:** Canada
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 93643 **N Exposed:** 1451 **N Unexposed:** 92192 **Mean age (years):** 30 **Diagnosis:**. Depression **Inclusion criteria:** Data used in this study came from 5 administrative sources housed in the British Columbia Linked Health Database26 (British Columbia registry of births, hospital separation records, the PharmaCare registry of subsidized prescriptions, physician billing records; and the registry of Medical Services Plan subscribers) linked to PharmaNet, a province-wide network recording all prescriptions dispensed by British Columbia pharmacists. A total of 203 520 registered live births in British Columbia occurred between April 1, 1997, and March 31, 2002. Of these, 200 291 (98.4%) had a valid study number that was linked to the mother's study number, and 192 725 (96.2%) of these records unambiguously matched hospital birth records. Of the 192 725, 191 452 (99.3%) reported estimated gestational ages between 11 and 59 weeks on the hospital separation record, which enabled us to estimate the date of conception. To ensure that the infants with long hospital stays were not underreported in our sample, we restricted our analysis to those with dates of conception before March 26, 2001, allowing 90 days between the last expected birth date and the last hospital separation date. To match maternal prescription records in the PharmaNet database, we further restricted the analysis to neonates with an estimated date of conception between January 1, 1998, and March 26, 2001, reducing our sample to 120 702. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** paroxetine (44.7%), fluoxetine (27.2%), sertraline (25.6%), fluvoxamine (4.6%), and citalopram (3.3%), plus others (for example venlafaxine) **Dosage:**
Outcomes	**Outcomes used:** Respiratory distress **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.22 OBERLANDER2008

Study ID	OBERLANDER2008
Bibliographic reference	Oberlander TF, Warburton W, Misri S, Riggs W, Aghajanian J, Hertzman C. Major congenital malformations following prenatal exposure to serotonin reuptake inhibitors and benzodiazepines using population-based health data. Birth Defects Research Part B – Developmental and Reproductive Toxicology. 2008b;83:68-76
Systematic review source	Gridoradias et al., 2013A; Ross et al., 2013; Wurst et al., 2010; Grigoriadis et al., 2013C
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical records **Country:** Canada
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 109945 **N Exposed:** 2625 **N Unexposed:** 107320 **Mean age (years):** 30 **Diagnosis:** NR **Inclusion criteria:** Data used in this study came from five administrative sources housed in the BC Linked Health Database (BC registry of births, hospital separation records, the PharmaCare registry of subsidized prescriptions; the Medical Services Plan physician billing records; and the registry of Medical Services Plan subscribers) linked to PharmaNet. The cohorts used in this study were assembled from records of 203,520 registered live births (hospital and home births) in British Columbia occurring between April 1, 1997 and March 31, 2002. To ensure accurate matching between all data sets, and accounting for data entry errors and records for multiple births, the final study cohort comprised records related to 119,547 live births, representing 92.7% of the live births in British Columbia. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations, congenital malformations, cardiac malformations, ASD **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Also reports data for benzodiazepines

1.23.23 PEDERSEN2009

Study ID	PEDERSEN2009
Bibliographic reference	Pedersen LH, Henriksen TB, Vestergaard M, Olsen J, Bech BH. Selective

	serotonin reuptake inhibitors in pregnancy and congenital malformations: population based cohort study. British Medical Journal. 2009;339:735
Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** medical birth registry **Country:** Denmark
Participants	**Trimester of exposure:** 1 **Duration of exposure:** 28 days before to 112 days after the beginning of gestation **Total N:** 494483 **N Exposed:** 1370 **N Unexposed:** 493113 **Mean age (years):** NR **Diagnosis:** Depression (although not explicit) **Inclusion criteria:** We used data from four Danish nationwide registries: the medical birth registry, the national register of medicinal product statistics, the fertility database, and the national hospital register. The registries were linked by the use of the unique personal identifier of 10 digits assigned to all citizens at birth. The medical birth registry16 stores data on all deliveries, including maternal age, maternal smoking status during pregnancy, parity, date of delivery, gestational age, birth weight, sex of newborn, and information on multiple pregnancy. Information on gestational age at birth is usually estimated from ultrasound measures during early pregnancy. In case of no ultrasound measure the last menstrual period is used. The initiation of pregnancy was calculated by subtracting day of birth by gestational age in days. The exposure window was defined as 28 days before to 112 days after the beginning of gestation. Exposure was defined as two or more redemptions of an SSRI in this time period (ATC codes N06AB). Women with only a single redemption in the exposure window were included in later analyses **Exclusion criteria:** Women with any redemption of insulin or antihypertensive medications in a period of three months before the estimated beginning of gestation and those with any redemption during the exposure window to other psychotropicmedications, such as antiepilepticmedication, antipsychotics, and anxiolytics. Antidepressants other than SSRIs, such as tricyclic antidepressants and venlafaxine, were excluded from the main analyses but included in later sensitivity analyses
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Fluoxetine, citalopram, paroxetine, sertraline **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, cardiac malformations, septal defects (ASD and/or VSD) **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.24 RAI2013

1.23.25 SIMON2002

Study ID	SIMON2002
Bibliographic reference	Simon GE, Cunningham ML, Davis RL. Outcomes of prenatal antidepressant exposure. The American Journal of Psychiatry. 2002;159:2055-61
Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013; Ross et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical records **Country:** US
Participants	**Trimester of exposure:** All trimesters **Duration of exposure:** NR **Total N:** 370 (sertraline), 418 (TCA) **N Exposed:** SSRI=185, TAC=209 **N Unexposed:** Unexposed SSRI conparison = 185, unexposed TCA control = 209 **Mean age (years):** NR **Diagnosis:**. NR **Inclusion criteria:** The study sample was drawn from the Group Health Cooperative, a prepaid health plan serving approximately 400,000 members in Washington State. The membership is generally representative of the area's population in terms of age, sex, ethnicity, and socioeconomic status. Because of contracts between Group Health Cooperative and the state of Washington, the 1996 membership included approximately 25,000 individuals covered by Medicaid and 12,000 covered by the Basic Health Plan, a statesubsidized program for low-income residents. Pharmacy records were used to identify all antidepressant prescriptions filled or refilled during the 360 days before delivery. Mothers with no antidepressant prescriptions during this period were considered unexposed. Those with any antidepressant prescriptions during the 270 days before delivery were considered exposed. The remaining patients (that is, those with antidepressant prescriptions filled in the period between 270 and 360 days before delivery) were classified as indeterminate and excluded from further analysis. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Fluoxetine, fluvoxamine, sertraline, paroxetine, amitriptyline, imipramine, doxepin, nortriptyline, protriptyline, desipramine **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, cardiac malformations, preterm delivery **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Mateched for maternal age, year of delivery, length of enrollment in health plan, lifetime antidepressant prescriptions filled and refilled, lifetime history of psychiatrictreatment (compared smoking, alcohol, other drug use)

1.23.26 SIVOJELEZOVA2005

Study ID	SIVOJELEZOVA2005
Bibliographic reference	Sivojelezova A, Shuhaiber S, Sarkissian L, Einarson A, Koren G. Citalopram use in pregnancy: prospective comparative evaluation of pregnancy and fetal outcome. American Journal of Obstetrics and Gynecology. 2005;193:2004-09
Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013; Ross et al., 2013
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Interview, medical records **Country:** Canada
Participants	**Trimester of exposure:** At least first trimester (54% continued throughout pregnancy) **Duration of exposure:** 39% first trimester, 50% through pregnancy **Total N:** 341 **N Exposed:** Citalopram=108, other SSRIs=115 **N Unexposed:** 118 **Mean age (years):** NR **Diagnosis:**. Depression **Inclusion criteria:** The women were recruited from the cohort of pregnant women or women planning pregnancy who contacted the Motherisk Program from 1999 to 2002 inquiring about the safety of citalopram and other medications in pregnancy. During an initial interview with a patient, a standardized intake form was completed over the telephone with information regarding general medical and obstetrical history, timing of drug exposure, and its dose schedule as well as information regarding exposures to alcohol, cigarettes, recreational drugs, chemicals, vitamins, radiation. At least 2 months after the expected date of confinement, all women were contacted for a telephone follow-up interview. The nonteratogen group (comparison group) was comprised of women with nonteratogenic exposures (eg, acetaminophen, hair dyes, vitamins, etc). The exposed group of women and the 2 comparison groups were matched for the maternal age (G 2 years) at the time of conception as well as the gestational stage of pregnancy (G 2 weeks) at the time of recruitment. **Exclusion criteria:** An exposure to a known teratogen or a xenobiotic with undetermined safety in pregnancy
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, other SSRIS **Dosage:** median 0.345 mgkg
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations preterm birth, spontaneous abortion **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Matched for maternal age, gestational age at time of recruitment (collected data on alcohol, smoking and other drugs)

1.23.27 SURI2007

Study ID	SURI2007
Bibliographic reference	Suri R, Altshuler L, Hellemann G, Burt VK, Aquino A, Mintz J. Effects of antenatal depression and antidepressant treatment on gestational age at birth and risk of preterm birth. American Journal of Psychiatry. 2007;164:1206-13
Systematic review source	Ross et al., 2013
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Interviews **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 44 **N Exposed:** 28 **N Unexposed:** 16 **Mean age (years):** 34 **Diagnosis:** Depression **Inclusion criteria:** Subjects were recruited from outpatient obstetrician-gynecologist practices or from the UCLA outpatient Women's Life Center psychiatric clinic. Primary inclusion criteria consisted of outpatient women between the ages of 18 and 45 in the first trimester of pregnancy with either a history of major depressive disorder or no psychiatric history (for the control group). All subjects underwent a Structured Clinical Interview for DSM-IV at study entry (Spitzer et al., 1995). Subjects were then followed once in each trimester with administration of the Center for Epidemiologic Studies Depression Scale (CES-D) (Radloff, 1997). Subjects with a CES-D score greater than 16 at any measured time were considered to have symptoms of depression. **Exclusion criteria:** presence of psychotic symptoms, the use of medications that are known to adversely affect the fetus, the use of other psychotropic medications, the presence of suicidality, and the use of alcohol, cigarettes, or substances while pregnant.
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Fluoxetine **Dosage:** NR
Outcomes	**Outcomes used:** Preterm delivery **Outcomes not used:** N/A
Study design	Cohort
Source of funding	
Limitations	
Notes	

1.23.28 WEN2006

Study ID	WEN2006
Bibliographic reference	Wen SW, Yang Q, Garner P, Fraser W, Olatunbosun O, Nimrod C, et al. Selective serotonin reuptake inhibitors and adverse pregnancy outcomes. American Journal of Obstetrics and Gynecology. 2006;194:961-66

Systematic review source	Gridoradias et al., 2013A; Myles et al., 2013; Ross et al., 2013; Wurst et al., 2010
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Maternal/infant/prescription records **Country:** Canada
Participants	**Trimester of exposure:** NR **Duration of exposure:** NR **Total N:** 4850 **N Exposed:** 972 **N Unexposed:** 3878 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** We first identified all live births and stillbirths in Saskatchewan to Saskatchewan residents between January 1, 1990, and December 31, 2000 (SSRIs were introduced into the Saskatchewan Formulary in 1989). These data were then linked with physician and hospital data files to compile services for infants up to 1 year after birth and with the registry file to identify any deaths within that 1-year period. Mothers were identified for each birth. For each mother, physician services, hospital separation, and outpatient prescription drug information was compiled for the period beginning 1 year before the date of birth. Pregnant women with at least 1 SSRI prescription that was dispensed in the 1-year period before delivery were selected as the exposed group. **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, fluoxetine, fluvoxamine, paroxetine, sertraline **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, preterm delivery, spontaneous abortion **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.29 WICHMAN2009

Study ID	WICHMAN2009
Bibliographic reference	Wichman CL, Moore KM, Lang TR, St Sauver JL, Heise Jr RH, Watson WJ. Congenital heart disease associated with selective serotonin reuptake inhibitor use during pregnancy. Mayo Clinic proceedings. 2009;84:23-7
Systematic review source	Gridoradias et al., 2013A; Gridoradias et al., 2013B ; Myles et al., 2013
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** medical records **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:**NR **Total N:** 25214 **N Exposed:** 808

	N Unexposed: 24406 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** After Mayo Clinic Institutional Review Board approval, conducted a retrospective cohort study examining all obstetric deliveries at Mayo Clinic's site in Rochester, MN, from January 1, 1993, to July 15, 2005. The Division of Obstetrics prospectively maintains an obstetric deliveries database that was used to aid with the medical record review. Identified 25,214 deliveries during that period. The obstetric database listed the medications a woman took during her pregnancy. Each case was then confirmed by review of each individual medical record. Pregnant women with a documented medication list during their pregnancy that included an SSRI or who were given at least 1 SSRI prescription during their pregnancy were selected as the exposed group, whereas the remaining 24,406 women were considered unexposed **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** Citalopram, escitalopram, paroxetine, fluoxetine, sertraline, venlafaxine (combined in data analysis) **Dosage: range:** median: 20 mg -75 mg
Outcomes	**Outcomes used:** Cardiac malformaions, VSD **Outcomes not used:** N/A
Study design	
Source of funding	NR
Limitations	
Notes	Data combined for all SSRIs over all trimesters

1.23.30 WISNER2009

Study ID	WISNER2009
Bibliographic reference	Wisner KL. Antidepressant use and preterm birth: reply. The American Journal of Psychiatry. 2009;166:1189-90
Systematic review source	Ross et al., 2013
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Delivery records and infant examinations **Country:** US
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 107 **N Exposed**: 71 **N Unexposed:** 36 **Mean age (years):** NR **Diagnosis:** Depression **Inclusion criteria:** Pregnant women 15-44 years old were recruited from two sites. Twenty-one were enrolled in Cleveland between Jan 23 2000, and April 1, 2001, and 217 were recruited in Pittsburgh between April 23, 2003, and July 11, 2007. Recruitment was by self-referral, physician referral, advertising, and screening in obstetrical ultrasound suites. After evaluating the patterns of SSRI

	and depression exposure that occurred in our subjects, we created five nonoverlapping groups: No SSRI, no depression; Continuous SSRI exposure; Continuous depression, no SSRI; Partial SSRI exposure; Partial depression, no SSRI. confirmed exposure (maternal serum level ≥10 ng/ml) for inclusion in the SSRI-treated groups **Exclusion criteria:** Women with active substance use disorder (identified by self-report or urine drug screen) or with gestational exposure to benzodiazepines or prescription drugs in the FDA-defined category of D or X
Interventions	**Drug class:** Antidepressants **Drug/s examined:** SSRIs **Dosage:** NR
Outcomes	**Outcomes used: Preterm delivery** **Outcomes not used:** N/A
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.23.31 WOGELIUS2006

Study ID	WOGELIUS2006
Bibliographic reference	Wogelius P, Norgaard M, Gislum M, Pedersen L, Munk E, Mortensen PB, et al. Maternal use of selective serotonin reuptake inhibitors and risk of congenital malformations. Epidemiology. 2006;17:701-4
Systematic review source	Myles et al., 2013
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Birth registries **Country:** Denmark
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** NR **Total N:** 4850 **N Exposed:** 972 **N Unexposed:** 3878 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** All female county residents who had a live birth or a stillbirth after the 20th week of gestation identified through the Danish Medical Birth Registry, which contains computerized records of all births in Denmark since 1 January 1973 **Exclusion criteria:** NR
Interventions	**Drug class:** Antidepressants **Drug/s examined:** SSRIs **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations **Outcomes not used:** N/A
Study design	Cohort

Source of funding	NR
Limitations	
Notes	

1.24 ANTIDEPRESSANTS – EXCLUDED STUDIES

Study	Reason for exclusion
Alwan S, Reefhuis J, Rasmussen SA, Olney RS, Friedman JM. Use of selective serotonin-reuptake inhibitors in pregnancy and the risk of birth defects. New England Journal of Medicine. 2007;356:2684-92	Single study outcomes
Andrade SE, McPhillips H, Loren D, Raebel MA, Lane K, Livingston Jet al. Antideperssant medication use and risk of persistent pulmonary hypertension of the newborn. Pharmacoepidemiology drug safety. 2009;18:246-252	Data could not be extracted
Bakker MK, Kerstjens-Frederikse WS, Buys CHCM, De Walle HEK, De Jong-van Den Berg LTW. First-trimester use of paroxetine and congenital heart defects: A population-based case-control study. Birth Defects Research Part A – Clinical and Molecular Teratology. 2010;88:94-100	Single study outcomes
Bakker MK, Kerstjens-Frederikse WS, Van den Berg MD, et al. Use of selective serotonin reuptake inhibitors in early pregnancy and risk of cardiac malformations. Pharmacoepidemiol Drug Safety. 2006;15:S81	Conference abstract
Berard A, Ramos E, Rey E, Blais L, St-Andre M, Oraichi D. First trimester exposure to paroxetine and risk of cardiac malformations in infants: the importance of dosage. Birth Defects Research Part B: Developmental and Reproductive Toxicology. 2006:80;18-27	No unexposed control group
Chambers C, Hernandez-Diaz S, Mitchell AA. "Selective Serotonin-Reuptake Inhibitors and Risk of Persistent Pulmonary Hypertension of the Newborn": comment Reply. The New England Journal of Medicine. 2006;354:2189-90	Single study outcomes
Chambers CD. Birth outcomes among pregnant women taking paroxetine (Paxil). 2007. Personal communication	Personal communication
Cole AJ, Ephross SA, Cosmatos IS, Walker AM. Paroxetine in the first trimester and the prevalence of congenital malformations. Pharmacoepidemiology and drug safety. 2007;16:1075-1085	No unexposed control group
Croen LA, Grether JK, Yoshida CK, Odouli R, Hendrick V. Antidepressant use during pregnancy and childhood autism spectrum disorders. Archives of General Psychiatry. 2011;68:1104-12	No disorder specific comparison group for autism outcomes
Einarson A, Pistelli A, SeSantis M, Malm H, Paulus WD, Panchaud A, et al. Evaluation of the Risk of Congenital Cardiovascular Defects Associated with Use of Paroxetine During Pregnancy. American Journal of Psychiatry. 2008:165;749-752	Data could not be extracted
Lewis AJ, Galbally M, Opie G, Buist A. Neonatal Growth Outcomes at Birth and Month Postpartum Following In Utero Exposure to Antidepressant Medication. Australian and New Zealand Journal of Psychiatry. 2010;44:482-487	Could not extract disaggregated SSRI data and % use of different antidepressants not reported
Louik C, Lin AE, Werler MM, Hernandez-Diaz S, Mitchell AA. First-trimester use of selective serotonin-reuptake inhibitors and the risk of birth defects. The New England Journal of Medicine. 2007;356;2675-2683	Data could not be extracted as total figures unclear
Malm H, Klaukka T, Neuvonen P. Risks associated with selective serotonin reuptake inhibitors in pregnancy. Obstetrics and Gynecology. 2005;106:1289-1296	Overlapping (but smaller) dataset than MALM2011
Nash CM, O'Connell CM, Howlett AA. Neonatal outcomes associated with maternal antidepressant use in a population cohort of Nova Scotian pregnancies between 1993 and 2004.Paediatr Child Health. 2007;12(SA):42	Conference abstract

Oberlander TF, Misri S, Fitzgerald CE, Kostaras X, Rurak, D, Riggs W (Pharamacologic factors associated with transient neonatal symptoms following prenatal. Psychotropic medication exposure. Journal of Clinical Psychiatry. 2004;65:230-237	Paper unavailable
Pastuszak A, Schick-Boschetto B, Zuber C, Feldkamp M, Pinelli M, Sihn S, et al. Pregnancy outcome following first-trimester exposure to fluoxetine (Prozac). JAMA.1993;5:2246-2248	Paper unavailable
Pearson KH, Nonacs RM, Viguera AC, Heller VL, Petrillo LF, Brandes M, et al. Birth outcomes following prenatal exposure to antidepressants. Journal of Clinial Psychiatry. 2007;68:1284-1289	Paper unavailable
Ramos E, St-Andre M, Rey E, Oraichi D, Berard A. Duration of antidepressant use during pregnancy and risk of major congenital malformations. British Journal of Psychiatry. 2008;192:344-50	Single study outcomes
Reis M, Kallen B. Delivery outcomes after maternal use of antidepressant drugs in pregnancy: an update using Swedish data. Psychological Medicine. 2010;40:1723-1733	Data could not be extracted as total figures unclear
Rompono J, Simmer K, ILett KF, Hackett LP, Doherty DA, Elliot R. Placental Transfer of SSRI and SNRI ANtidepressanrs and Effects on the Neonate. Pharmacopsychiatry.2009;42:95–100	Data cannot be extracted
Schloemp S, Paulus WE, Sterzik K, Stoz F. Congenital malformations after antidepressant medication with paroxetine in early pregnancy? [abstract] Human Reproduction. 2006;21(supplement 1):p. i12	Conference abstract
Sorensen MJ, Gronborg TK, Christensen J, Parner ET, Vestergaard M, Schendel D, el al. Antidepressant exposure in pregnancy and risk of autism spectrum disorders. Clinical Epidemiology.2013;5:449-459	Autism study- no disordered comparison group
Wilson KL, Zelig CM, Harvey JP, Cunningham BS, Dolinsky BM, Napolitano PG. Persistent pulmonary hypertension of the newborn is associated with mode of delivery and not with maternal use of selective serotonin reuptake inhibitors. American Journal of Perinatology. 2011;28:19-24	none of the cases were exposed to drugs,

1.25 ANTIPSYCHOTICS – INCLUDED STUDIES

1.25.1 AUERBACH1992

Study ID	AUERBACH1992
Bibliographic reference	Auerbach JG, Hans SL, Marcus J, Maeir S. Maternal psychotropic medication and neonatal behavior. Neurotoxicology & Teratology. 1992;14:399-406
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Not reported **Country:** Israel **Matching**: No **Blindness**: Yes **Raters**: Trained research staff
Participants	**Trimester of exposure:** 3 **Duration of exposure:** Not reported **Total N:** 58 infants, 54 mothers **N Exposed:** 14 **N Unexposed:** 44 **Mean age (years):** 27.6 (healthy, no medication); 28.4 (ill, no medication); 28.4 (ill, medication) **Diagnosis:** Maternal diagnosis categories for infants of mothers in the ill-medication group: 64.29% schizophrenia; 7.14% major depression; 7.14% histrionic personality disorder; 7.14% antisocial personality disorder; 7.14% affective disorder; 7.14% bipolar manic. **Inclusion criteria:** Fifty-four women were recruited during their last trimester of pregnancy between the years of 1973 and 1977. **Exclusion criteria:** NR
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** First-generation antipsychotics (neuroleptics) **Dosage:** Antipsychotics: Chlorpromazine 25-250 mg/day; fluphenazine hcl 1.5 mg/day – 25 mg/week; perphenazine 8 mg/day; thioridazine hcl 40-100 mg/day; trifluoperzine 9 mg/day. Other psychotropic drugs: Diazepam 10 mg/day; chlordiazepoxide NR; lithium 600 mg/day; nitrazepam 5 mg/day; opipramol 30 mg/day; medazepam 15 mg/day.
Outcomes	**Outcomes used:** Birthweight, Brazelton Neonatal Behavioral Assessment Scale **Outcomes not used:**
Study design	Cohort
Source of funding	Collection of infancy data was supported by grants from the US-Israel Binational Science Foundation (Grant 598), the Chief Scientist's Office of the Israel Ministry of Health, and the Olivetti Foundation. Analysis of data was supported by a grant from the Scottish Rite Schizophrenia Research Program.
Limitations	1. One mother in the ill-medicated group and none in the ill-no medication group reported drinking on a regular basis; there was a trend for mothers in the ill-medicated group to be of lower SES than the unmedicated group
Notes	i. Data refer to 14 day follow-up – 3 day follow-up not extracted; iii. Twelve of the ill mothers were receiving antipsychotic and antianxiety medication during the final trimester of pregnancy.

1.25.2 BODEN2012A

Study ID	BODEN2012A
Bibliographic reference	Boden R, Lundgren M, Brandt L, Reutfors J, Andersen M, Kieler H. Bipolar disorder, mood stabilizers and adverse pregnancy outcome-a population based cohort study. Pharmacoepidemiology and Drug Safety. 2012a;21:31
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** SE
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 667/331376[1] **N Exposed:** 113 **N Unexposed:** 554/331263[1] **Mean age (years):** Unexposed bipolar: 16.8% <25; 58.5% 25-34; 24.7% = >35; Exposed: 18.4% <25; 60.3% 25-34; 21.3% = >35. **Diagnosis:** Bipolar disorder **Inclusion criteria:** Women with a last menstrual period anytime after 1 July 2005 and giving birth (to a singleton) anytime before the end of 31 December 2009. Women with a record of at least two bipolar diagnoses were identified and grouped as treated—those who had filled a prescription for mood stabilisers (lithium, antipsychotics, or anticonvulsants) during pregnancy—or untreated. We defined use of a mood stabiliser as filling a prescription that supplied a quantity of the drug to cover intake during pregnancy according to the prescribed dosage. **Exclusion criteria:** Excluded women with missing data on smoking, height, or cohabitation, as well as those giving birth to a stillborn infant.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformation, gestational diabetes, preterm delivery, large for gestational age, small for gestational age, caesarean section **Outcomes not used:** Instrumental delivery, non-spontaneous start of delivery, head circumference, APGAR score
Study design	Cohort
Source of funding	This study was funded by unrestricted grants from Lennanders Foundation, Gillbergska Foundation, Uppsala County Council (ALF-grants), and by the authors' affiliations.
Limitations	
Notes	[1] Number using unexposed general population/disordered comparions Also data for other 'mood stablisers' including lamotrigine, lithium, valproate and carbamazepine.

1.25.3 BODEN2012B

Study ID	BODEN2012B
Bibliographic reference	Boden R, Lundgren M, Brandt L, Reutfors J, Andersen M, Kieler H. Risks of adverse pregnancy and birth outcomes in women treated or not treated with

	mood stabilisers for bipolar disorder: Population based cohort study. BMJ (Online). 2012b;345
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** SE
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 358203 **N Exposed:** 507 **N Unexposed:** 357696 **Mean age (years):** 14.6% <25; 63.7% 25-34; 21.7% = >35. **Diagnosis:** Exposed groups: 90.3% any psychiatric diagnosis; 20.9% schizophrenia; 17.6% other nonaffective psychosis; 11.2% bipolar disorder. Non-exposed group: 8.7% any psychiatric diagnosis; 0.03% schizophrenia; 0.1% other nonaffective psychosis; 0.2% bipolar disorder. **Inclusion criteria:** All women giving birth in Sweden from July 1, 2005, through December 31, 2009, grouped by filled prescriptions for (1) olanzapine and/or clozapine, the most obesogenic and diabetogenic antipsychotics, (2) other antipsychotics, or (3) no antipsychotics. Exposure was defined as filling a prescription for an antipsychotic (Anatomical Therapeutic Chemical code N05A) from last menstrual period to parturition. **Exclusion criteria:** Excluded prochlorperazine, levomepromazine, and melperone prescriptions because these drugs are mainly used as antiemetics or anxiolytics with low and intermittently administrated doses. Lithium, which also belongs to the Anatomical Therapeutic Chemical category N05A,was excluded because of its different pharmacological action and placental passage compared with the other compounds in the N05A group and because it is mainly used to treat bipolar disorder.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Gestational diabetes, still birth **Outcomes not used:** Birth weight, birth length, head circumference
Study design	Cohort
Source of funding	This study was supported by unrestricted grants from the Lennander's Foundation and Gillbergska Foundation.
Limitations	
Notes	Unable to use birth weight and length outcomes as unajusted event rates not reported. DATA REQUEST Unadjusted ORs for all outcomes for group 1 and group 2 comparison or N births (so can convert reported % to compare events/people in each group)

1.25.4 DIAV-CITRIN2005

Study ID	DIAV-CITRIN2005
Bibliographic reference	Diav-Citrin O, Shechtman S, Ornoy S, Arnon J, Schaefer C, Garbis H, et al. Safety of haloperidol and penfluridol in pregnancy: a multicenter, prospective, controlled study. Journal of Clinical Psychiatry. 2005;66:317-22

Methods	**Prospective/Retrospective:** Prospective **Data collection:** Mixed **Country:** IL
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 846 **N Exposed:** 215 **N Unexposed:** 631 **Mean age (years):** Butyrophenone Group median age = 32; Control median age = 30. **Diagnosis:** Butyrophenone group: psychosis (33.5%), schizophrenia (10.7%), depression (9.3%). bipolar disorder (4.2%). schizoaffective disorder (1.4%), anxiety (1.4%). panic attacks (0.9%). hyperemesis gravidarum (0.5%), borderline personality (0.5%), suicide attempt (0.5%), substance abuse (0.5%), and Tourette syndrome (0.5%). In 36.1% of the cohort, the indication for therapy was not specified. **Inclusion criteria:** Pregnant women who (or whose physician or midwife) contacted one of 4 teratology information services (TISs) seeking counseling in regard to gestational exposure to haloperidol or penfluridol between the years 1989 and 2001. The 4 participating centers were the Israeli TIS (Jerusalem, Israel), Beratungsstelle ftir Embryonaltoxikologie (Berlin, Germany), TIS (Bilthoven, The Netherlands), and Servizio di Informazione Teratologica (Padova, Italy). The butyrophenone-exposed group was compared to an ENTIS control group of women who had been counseled during pregnancy in regard to exposures known to be nonteratogenic from the 4 participating centers. In order to increase the power of our study, we tried to reach a I:3 ratio between the exposed (haloperidol or penfluridol) and control groups. **Exclusion criteria:** 19 cases were excluded for lack of data on duration of treatment.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** NR **Dosage:** The median daily oral dose of haloperidol was 5 mg (2.25-10 mg), the median parenteral dose of haloperidol was 100 mg/4 weeks (50-100 mg), the median oral dose of pentluridol was 20 mg/week (20-40 mg).
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations, miscarriage, still birth, ceasarean section, preterm delivery **Outcomes not used:** Eptopic pregnancy, livebirth, limb defect
Study design	Cohort
Source of funding	NR
Limitations	
Notes	DATA REQUEST. Outcomes with median data not extracted – request mean (SD).

1.25.5 HABERMANN2013

Study ID	HABERMANN2013
Bibliographic reference	Habermann F, Fritzsche J, Fuhlbruck F, Wacker E, Allignol A, Weber-Schoendorfer C, et al. Atypical antipsychotic drugs and pregnancy outcome: a prospective, cohort study. Journal of Clinical Psychopharmacology.

	2013;33:453-62
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records and interview **Country:** GE
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 1967 **N Exposed:** 845 **N Unexposed:** 1122 **Mean age (years):** 32 **Diagnosis:** Exposed: 51.4% psychotic disorders (not otherwise specified); 19.2% schizophrenia; 23.7% depression; 4.9% bipolar affective disorders; anxiety disorders 7%. **Inclusion criteria:** Inclusion criteria for prospective cases were the absence of prenatal pathologic findings and that the outcome of pregnancy was not known. The study cohort consists of women exposed to at least 1 SGA during pregnancy; comedication with FGAs was allowed. Comparison cohort I consists of women exposed to FGAs excluding comedication with SGAs. (Comparison cohort II were pregnant women using drugs known as not harmful to the unborn). **Exclusion criteria:** For the comparison cohort II, women exposed to teratogenic, fetotoxic, or insufficiently studied agents were excluded as described elsewhere. For example, sufficiently studied mild analgesics (paracetamol, ibuprofen during first trimester), antiasthmatics (inhalative glucocorticoids and A2-sympathomimetics), antiemetics (meclozine, metoclopramide, dimenhydrinate), anti-infectives like penicillins and cephalosporins, heparins, vaccines (eg, diphtheria toxoid, tetanus toxoid, and seasonal influenza vaccine), antacids except for long-term use of aluminum-containing drugs, dietary supplements (iodide, folic acid, vitamins) or cosmetic or hair coloring products were used by women of the comparison cohort II. Cases with potentially embryo- or fetotoxic drugs were not excluded for both the study cohort and the comparison cohort I but were assessed afterward.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, cardiac malformations, stillbirth, misacrriage, preterm delivery **Outcomes not used:** Minor congenital malformations, elective termination of pregnancy, livebirth
Study design	Cohort
Source of funding	German Federal Ministry of Health
Limitations	
Notes	Unexposed comparison = pregnant women taking drugs known as not harmful to the unborn child.

1.25.6 JOHNSON2012

Study ID	JOHNSON2012

Bibliographic reference	Johnson KC, LaPrairie JL, Brennan PA, Stowe ZN, Newport DJ. Prenatal antipsychotic exposure and neuromotor performance during infancy. Archives of General Psychiatry. 2012;69:787-94
Methods	**Prospective/Retrospective:** Prospective **Data collection:** **Mixed** **Country: US**
Participants	**Trimester of exposure:** Any **Duration of exposure:** NR **Total N:** 107 **N Exposed:** 22 **N Unexposed:** 85 **Mean age (years):** 34 **Diagnosis:** Exposed: 36.4% depressive disorder; 31.8% bipolar disorder; 50% anxiety disorder; 9.1% psychotic disorder. Non-exposed: 14.1% depressive disorder; 3.5% bipolar disorder; 15.3% anxiety disorder; 0% psychotic disorder (DSM-IV) **Inclusion criteria:** To be included in the study, maternal medication history during pregnancy had to meet 1 of the following criteria: (1) at least 1 antipsychotic medication, (2) at least 1 antidepressant medication, or (3) no psychotropic exposure. There was no minimum level of exposure required for inclusion and dosage and timing varied according to patient need **Exclusion criteria:** Mothers prescribed antiepileptic drugs during pregnancy were removed from the sample to isolate the potential effects of antipsychotic medications, and mothers only prescribed anxiolytics or hypnotics were excluded because of the small group size. Additional exclusion criteria included active maternal DSM-IV substance use disorder (abuse or dependence except for nicotine dependence) within 6 months of conception as determined by Structured Clinical Interview for DSM-IV-TR (SCID) and the presence of infant congenital abnormalities. Multiple gestation was not an exclusion criterion, and the sample included 2 sets of twins
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any antipsychotic **Dosage:** NR
Outcomes	**Outcomes used:** Infant Neurological International Battery **Outcomes not used:** NR
Study design	Cohort
Source of funding	
Limitations	
Notes	1 majority prospective 2 Number refers to N at start of study. N after attirition NR but attrition equivalent across groups (8.7% of total sample). Contacted authors fo data but no response

1.25.7 LIN2010

Study ID	LIN2010
Bibliographic reference	Lin HL, Chen YH, Lin HC. No increase in adverse pregnancy outcomes for women receiving antiepileptic drugs. Journal of Neurology. 2009;256:1742-49
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries

	Country: TW
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** 23 **Total N:** 4176 **N Exposed:** 242 **N Unexposed:** 3934 **Mean age (years):** 3.5% <20; 15.1% 20–24; 33.3% 25–29; 32.9% 30–34; 15.2% and >34 years) **Diagnosis:** Schizophrenia **Inclusion criteria:** We used population-based data from the Taiwan National Health Insurance Research Database and birth certificate registry covering the years 2001 to 2003. In total, 696 mothers with schizophrenia and 3480 matched unaffected mothers were included for analysis. We only selected patients who had at least three consensus schizophrenia diagnoses for the study cohort. We randomly chose 3480 mothers (five for every mother with schizophrenia) matched with the study group according to age, the year of delivery, hypertension, and diabetes. **Exclusion criteria:** Mothers were excluded who had taken both typical and atypical antipsychotics during their pregnancies, mothers who have received injectable antipsychotics, antiepileptics or lithium during pregnancy, and mothers who had taken either typical or atypical antipsychotics less than 30 days during pregnancy. The comparison cohort excluded mothers who had once been diagnosed with any type of mental disorder (ICD-9-CM codes 290–319) or chronic diseases (such as systemic lupus erythematosis, rheumatoid arthritis, gout, sarcoidosis, or ankylosing spondylitis) between 1996 and 2003.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Birthweight (small for gestational age, large for gestational age,), Low birthweight <2500g, preterm delivery **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Comparison group had a psychiatric diagnosis

1.25.8 MCKENNA2005

Study ID	MCKENNA2005
Bibliographic reference	McKenna K, Koren G, Tetelbaum M, Wilton L, Shakir S, Diav-Citrin O, et al. Pregnancy outcome of women using atypical antipsychotic drugs: a prospective comparative study. Journal of Clinical Psychiatry. 2005;66:444-49
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Mixed **Country:** Multiple
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported

	Total N: 302 **N Exposed:** 151 **N Unexposed:** 151 **Mean age (years):** NR **Diagnosis:** Exposed group: 29% depression. 24% schizophrenia. 18% bipolar disorder. 2% schizoaffective. 7% psychotic episode, 5% psychotic depression. 2% obsessive-compulsive disorder,1% posttraumatic stress disorder. and 1% schizophreniform disorder. Some women had more than I diagnosis. and some women were unsure of their diagnosis. **Inclusion criteria:** Included pregnant women who contacted the Motherisk Program in Canada or the Israeli Teratogen Information Service in Israel and women who were recruited from the Drug Safety Research Unit database in England. Women who had been exposed to atypical anti psychotics were matched to a comparison group of pregnant women who had not been exposed to these agents. Women who were identified as having taken an atypical antipsychotic within 3 months of pregnancy or during pregnancy were followed up prospectively. (Women in the comparison group were matched to the control group for maternal age plus or minus 2 years and gestational age at time of call plus or minus 2 weeks). **Exclusion criteria:** Women who reported a psychiatric diagnosis or psychotropic medication use were excluded from the comparison group.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Second-generation antipsychotics (atypical antipsychotic drugs) **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformaion, birthweight, miscarriage, stillbirth, preterm delivery **Outcomes not used:** Live birth, gestational age at delivery
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.25.9 NEWHAM2008

Study ID	NEWHAM2008
Bibliographic reference	Newham JJ, Thomas SH, MacRitchie K, McElhatton PR, McAllister-Williams RH. Birth weight of infants after maternal exposure to typical and atypical antipsychotics: prospective comparison study. British Journal of Psychiatry. 2008;192:333-37
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** GB
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 108 **N Exposed:** 70 **N Unexposed:** 38 **Mean age (years):** 31

	Diagnosis: Not reported **Inclusion criteria:** Only babies born after full-term deliveries to mothers exposed to antipsychotics in therapeutic doses or one of the reference medications were included in the analyses. For the antipsychotic groups, cases of monotherapy with a single antipsychotic and antipsychotic exposure with more than a single therapeutic agent (including over-the-counter medicine) were included. For a reference group, the database was searched for a list of drugs compiled by the NTIS considered to be non-teratogenic and with no associated foetal or adult weight side-effects. **Exclusion criteria:** Postdate deliveries (gestational age >42 weeks) were excluded. Cases where exposure occurred to both a typical and atypical antipsychotic were not included. Exclusion criteria were if the infant displayed congenital malformations, maternal diabetes was recorded or if there was missing birth weight, gestational age or gender data. Nine infants exposed to typical (16%) and 5 exposed to atypical (17%) antipsychotics were excluded owing to premature birth, and 2 infants exposed to typical antipsychotics (4%) were excluded for postdatism.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Birthweight, Small for gestational age, large for gestational age **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.25.10 PENG2013

Study ID	PENG2013
Bibliographic reference	Peng M, Gao K, Ding Y, Ou J, Calabrese JR, Wu R, et al. Effects of prenatal exposure to atypical antipsychotics on postnatal development and growth of infants: a case-controlled, prospective study. Psychopharmacology. 2013;228:577-84
Methods	**Prospective/Retrospective:** Prospective **Data collection: Questionnaires,** **Country:** China
Participants	**Trimester of exposure:** Any trimester **Duration of exposure:** Not reported **Total N:** 152 **N Exposed:** 76 **N Unexposed:** 76 **Mean age (years):** 30 **Diagnosis:** Schizophrenia (DSM-IV) **Inclusion criteria:** Women with a diagnosis of schizophrenia based on medical records and singleton pregnancy at more than 38 weeks. Those who met the criteria of DSM-IV diagnosis of schizophrenia and were taking a targeted antipsychotic agent including clozapine, olanzapine, risperidone, sulpiride or

	quetiapine throughout the pregnancy were recruited. Control cases were recruited similarly among the women who were seeking prenatal care but did not have any mental disorder and were not treated with any antipsychotics **Exclusion criteria:** All expectant mothers were excluded from the study if they had evidence of liver or renal dysfunction, diabetes mellitus, or cardiovascular diseases during their pregnancy
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** clozapine (n=33), risperidone (n=16), sulpiride (n=13), olanzapine (n=8), and quetiapine (n=6) **Dosage:** Clozapine 178.03 mg; Risperidone 2.06 mg; Sulpiride 461.54 mg; Olanzapine 7.81 mg; Quetiapine 550 mg.
Outcomes	**Outcomes used:** Bayley scales of Infant develoment **Outcomes not used:**
Study design	Cohort
Source of funding	World Psychiatric Association
Limitations	
Notes	This study was included, despite having single study outcomes as the data on antipsychotics was very limited

1.25.11 REIS2008

Study ID	REIS2008
Bibliographic reference	Reis M, Kallen B. Maternal use of antipsychotics in early pregnancy and delivery outcome. Journal of clinical psychopharmacology. 2008;28:279-88
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** SE
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 976738 **N Exposed:** 2971 **N Unexposed:** 973767 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** Women who had reported the use in early pregnancy of antipsychotics were identified, and maternal characteristics and pregnancy outcome were compared with all other women in the register. Because recording of maternal drug use began July 1, 1994, births from July 1, 1995 up to and including 2005 were studied. **Exclusion criteria:** NR
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformation, major congenital malformation, birthweight (small for gestational age and large for gestational age), gestational diabetes, still birth, ceasarean delivery, preterm delivery **Outcomes not used:**

Study design	Cohort
Source of funding	Supported by a grant from Evy and Gunnar Sandberg Foundation to B.K
Limitations	
Notes	

1.25.12 SADOWSKI2013

Study ID	SADOWSKI2013
Bibliographic reference	Sadowski A, Todorow M, Brojeni PY, Koren G, Nulman I. Pregnancy Outcomes following Maternal exposure to Second-generation antipsychotics given with other psychotropic drugs: a cohort study. BMJ Open. 2013;3
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records and interview **Country:** CA
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** 31 **Total N:** 266 **N Exposed:** 133 **N Unexposed:** 133 **Mean age (years):** NR **Diagnosis:** Exposed group: 36.8% bipolar disorder; 27.1% depression; 9.8% anxiety and depression; 9.8% sleep disorders; 3% schizophrenia; 1.5% schizoaffective disorders. **Inclusion criteria:** All potential participants were identified from a database of women who directly contacted the Motherisk Program at the Hospital for Sick Children in Toronto, Canada, between 2005 and 2009. Women who initially called the service to inquire about the safety of an SGA and who confirmed the use of this medication for a minimum of 4 weeks of pregnancy were invited to participate. A comparison group was comprised of women who contacted Motherisk between 2005 and 2009, and reported exposure to non-teratogenic agents (eg, acetaminophen, antihistamines, etc). **Exclusion criteria:** Mothers exposed to teratogenic medications unrelated to their psychiatric disorder treatment, such as acutane, or who abused substances (eg, alcohol, marijuana, cocaine, heroin, etc) were excluded from the study cohort. Fertility-assisted pregnancies, twin/triplet pregnancies or pregnancies with known outcomes at the initial time of contact (eg, contacted Motherisk following the birth, reported abnormal pregnancy screening tests and/or ultrasounds) were excluded from the exposed and comparison groups. Moreover, control women who reported a history of psychiatric disorders or who were exposed in their current pregnancy to a known teratogen were excluded.
Interventions	**Drug class:** Antipsychotics **Drug/s examined:** Second-generation antipsychotics (atypical antipsychotic drugs) **Dosage:** Quetiapine 25 mg/day-400 mg/day; Fluoxetine 80 mg/day; Clonazepam 0.5 mg/day; Zoplicone 7.5 mg/day; Citalopram 20-60 mg/day; Atomextine 40 mg/day; Sertraline 50-150 mg/day; Olanzapine 2.5 mg/day. (For exposed, malformation group).

Outcomes	**Outcomes used:** Congenital malformation, birthweight (small for gestational age and large for gestational age), ceasarean delivery **Outcomes not used:**
Study design	Cohort
Source of funding	Motherisk Funds.
Limitations	
Notes	

1.26 ANTIPSYCHOTICS – EXCLUDED STUDIES

Study	Reason for exclusion
Kulkarni J, McCauley-Elsom, K, Marston N, Gilbert H, Gurvich C, de Castella, A et al. Preliminary findings from the National Register of Antipsychotic Medication in Pregnancy. Australian & New Zealand Journal of Psychiatry. 2008;42: 38-44 Kulkarni J, Gilbert H, Gurvich C, Lee S, Marston N, McCauley K, et al. The national register of antipsychotic medication in pregnancy (NRAMP): The first one hundred babies. Australian and New Zealand Journal of Psychiatry. 2010;44: A45.	No unexposed control group
Newport DJ, Calamaras MR, DeVane CL, Donovan J, Beach AJ, Winn S et al. Atypical antipsychotic administration during late pregnancy: Placental passage and obstetrical outcomes. American Journal of Psychiatry. 2007;164: 1214-1220	No unexposed control group
Wichman CL. Atypical antipsychotic use in pregnancy: A retrospective review. Archives of Women's Mental Health. 2009;12: 53-57	No unexposed control group
Yaris F, Ulku C, Kesim M, Kadioglu M, Unsal M, Dikici MF, et al. Psychotropic drugs in pregnancy: a case-control study. Prog Neuropsychopharmacol Biol Psychiatry. 2005;29:333–338	Does not disaggregate by drug class

1.27 ANTICONVUSANTS – INCLUDED STUDIES

1.27.1 ADAB2004/VITEN2005

Study ID	ADAB2004/VINTEN2005
Bibliographic reference	Adab N, Kini U, Vinten J, Ayres J, Baker G, Clayton-Smith J, et al. The longer term outcome of children born to mothers with epilepsy. Journal of Neurology, Neurosurgery and Psychiatry. 2004;75:1575-83 Vinten J, Adab N, Kini U, Gorry J, Gregg J, Baker GA. Neuropsychological effects of exposure to anticonvulsant medication in utero. Neurology. 2005;64:949-54
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical records **Country:** GB
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** Unclear **N Exposed:** Unclear **N Unexposed:** Unclear **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Mothers with epilepsy were recruited retrospectively from specialist epilepsy clinics and obstetric clinics from the Liverpool and Manchester region. A total The study included women with a diagnosis of epilepsy who had children aged between 6 and 16 years. **Exclusion criteria:** Women were excluded from the study if they had a progressive neurologic deficit, a major learning difficulty (defined as inability to live independently), or symptomatic generalized epilepsy. Approval for the study protocol was obtained by the North West multi-center and local research ethics committee.
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine; Valproate **Dosage:** NR
Outcomes	**Outcomes used:** Verbal IQ, performance IQ, full scale IQ **Outcomes not used:** Educational problems
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.2 ARTMA2005

Study ID	ARTAMA2005
Bibliographic reference	Artama M, Auvinen A, Raudaskoski T, Isojarvi I, Isojarvi J. Antiepileptic drug use of women with epilepsy and congenital malformations in offspring. Neurology. 2005:64;1874-1878.

Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records **Country:** FI
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 2350 **N Exposed:** 1411 **N Unexposed:** 939 **Mean age (years):** 28 **Diagnosis:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Patient population in this study was obtained from the SII database. Identified all women who became eligible for full reimbursement for AEDs with epilepsy as indication for the first time between January 1, 1985, and December 31, 1994, and who were alive on January 1, 1990. Children born to the women in the cohort from 1991 to 2000 were identified from the Medical Birth Register maintained by the National Research and Development Centre for Welfare and Health. Information included the personal identification numbers of the mothers and their children, as well as the numbers of babies.Only children born after diagnosis of maternal epilepsy and born during the study period were included in the analyses **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.3 ARATMA2013

Study ID	ARTAMA2013
Bibliographic reference	Artama M, Gissler M, Malm H, Ritvanen A. Effects of maternal epilepsy and antiepileptic drug use during pregnancy on perinatal health in offspring: Nationwide, retrospective cohort study in Finland. Drug Safety.2013:36;359-369
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** Finland
Participants	**Trimester of exposure:** at least 3rd trimestet **Duration of exposure:** Not reported **Total N:** 4867 **N Exposed:** 3067 **N Unexposed:** 1800 **Mean age (years):** 79% 20-34 **Diagnosis:** Epilepsy

	Diagnosis of unexposed group: Epilepsy **Inclusion criteria:** The data were obtained from the Finnish national health registers: the Medical Birth Register (MBR), the Finnish Malformation Register, the Special Refund Entitlement Register and the Register on Reimbursement Drugs. Information from the different registers was merged through record linkages, based on the unique personal identification numbers assigned to all Finnish citizens and permanent residents.Inclusion criteria of the study groups varied in the analyses by outcomes: (a) singleton births: CS and ECS, perinatal death; (b) singleton live births: preterm birth, low birth weight, SGA, LGA and infant death; and (c) full-term singleton live births: low Apgar score, need for respiratory treatment and admission to neonatal care unit. In the last group, AED-exposed offspring of WWE included only those with at least third-trimester exposure. **Exclusion criteria:** Births with AED exposure without maternal epilepsy diagnosis were excluded, and persons with epileptic symptoms on AED treatment but no confirmed diagnosis
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, lamotrigine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Admission to neonatal care, Stillbirth/perinatal death, preterm birth **Outcomes not used:** respiratory treatment, low birthweight, large for gestational age, small for gestational age, APGAR score <7
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	1. Used epilepsy comparison group 2. Unable to use additional outcomes as could not be combined in meta-analysis

1.27.4 BODEN2012A

See 1.25.2.

1.27.5 BORTHEN2011

Study ID	BORTHEN2011
Bibliographic reference	Borthen I, Eide MG, Daltveit AK, Gilhus NE. Obstetric outcome in women with epilepsy: a hospital-based, retrospective study. BJOG: an International Journal of Obstetrics and Gynaecology. 2011;118:956-65
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Telephone interview and physician verification via letter **Country:** NO
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 205 **N Exposed:** 116 **N Unexposed:** 89

	Mean age (years): 29 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** General population **Inclusion criteria:** The epilepsy deliveries were divided into two groups according to the mother's epilepsy: (i) those with epileptic seizures occurring <5 years before conceiving according to the neurological case record (termed 'active epilepsy'); and (ii) those with seizures 5 years or more before conceiving (termed 'nonactive epilepsy'). We identified the type of epilepsy according to the hospital case records made by a neurologist. We classified epilepsy as either generalised or focal, and as unspecified if the woman could not be assigned to either of the two groups. The control group of 205 women without epilepsy was recruited and identified from MBRN. For each delivery in the epilepsy group, one control was randomly selected among the deliveries in the same week at the same hospital as the case with epilepsy, and matched for age and parity. These control women received a written enquiry for participation in the study. If a woman did not consent, a new delivery control was selected **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	Norwegian Research Council through the NevroNor research programme.
Limitations	
Notes	Focus of the study was to determine complications as a result of epilepsy (rather than the effects of AEDs). Extracted epilepsy exposed use vs epilepsy unexposed. Only disaggregated individual drug data available for major congenital malformations. All other outcomes for all anitconvulsants combined therefore could no be used.

1.27.6 BROSH2011

Study ID	BROSH2011
Bibliographic reference	Brosh K, Matok I, Sheine E, Koren G, Wiznitzer A, Gorodischer R, et al. Teratogenic determinants of first- trimester exposure to antiepileptic medications. Journal of Population Therapeutics and Clinical Pharmacology. 2011;18:e89-e98
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** IL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 100736 **N Exposed:** 421 **N Unexposed:** 100315 **Mean age (years):** 29 **Diagnosis:** Not reported **Diagnosis of unexposed group:** General population

	Inclusion criteria: The exposed group comprised mothers to whom antiepileptic medications were dispensed during the first trimester of pregnancy (up to 13 weeks of gestation). The first day of the last menstrual period was considered the first day of gestation. **Exclusion criteria:** Women who were exposed to dihydrofolate reductase inhibitors (sulfamethoxazole/trimetoprim and methotrexate) during the first trimester
Interventions	**Drug class:** Valproate **Drug/s examined:** **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	Computer Units of Clalit Southern District and Soroka Medical Center
Limitations	
Notes	Only diaggagated data for valproate- major congenital malformations could be used. All other outcomes not diaggregated by indiviudla anticonvulsant

1.27.7 BURJA2006

Study ID	BURJA2006
Bibliographic reference	Burja S, Rakovec-Felser Z, Treiber M, Hajdinjak D, Gajsek-Marchetti M. The frequency of neonatal morbidity after exposure to antiepileptic drugs in utero: a retrospective population-based study. Wiener Klinische Wochenschrift. 2006;118:12-16
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Hospitals **Country:** SI
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 69 **N Exposed:** 37 **N Unexposed:** 32 **Mean age (years):** NR **Diagnosis:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** Feeding problems, intercranial hemorrhage. Small for gestational age, withdrawal symptoms
Study design	Cohort
Source of funding	N/R

Limitations	
Notes	Outcomes not used as could not be combined in meta-analysis, or the deifnition of the outcome unclear

1.27.8 CANGER1999

Study ID	CANGER1999
Bibliographic reference	Canger R, Battino D, Canevini MP, Fumarola C, Guidolin L, Vignoli A, et al. Malformations in offspring of women with epilepsy: a prospective study. Epilepsia. 1999;40:1231-36
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Hospitals **Country:** IL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 452 **N Exposed:** 427 (313 monotherapy) **N Unexposed:** 25 **Mean age (years):** 28 **Diagnosis:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Women were referred to us either by the Epilepsy Center of the San Paolo Hospital or by other Epilepsy Centers in the Lombardy region. Qur population is made up of women from different sociocultural backgrounds, mainly from the Milan metropolitan and suburban areas, although women from other Italian regions were also included in the study. All women were entered in the study before the twentieth week of gestation. The patients received monthly obstetric and neurologic examinations, and AED blood levels were tested monthly. Only first-trimester plasma AED concentrations were included in the data analysis. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformations, major congenital malformations **Outcomes not used:** Deformities
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.9 CASSINA2013

Study ID	CASSINA2013
Bibliographic reference	Cassina M, Dilaghi A, Di Gianantonio E, Cesari E, De Santis M, Mannaioni G, et al. Pregnancy outcome in women exposed to antiepileptic drugs: teratogenic role of maternal epilepsy and its pharmacologic treatment. Reproductive

	Toxicology. 2013;39:50-57
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview **Country:** IT
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 1177 **N Exposed:** 310 **N Unexposed:** 867 **Mean age (years):** 33 **Diagnosis of exposed group:** 57.7% depression, 13.9% anxiety **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Inclusion criterion for the study group was exposure to an AED between the 5th and the 14th week after their last menstrual period. Of the non-epileptic exposed 58% had mood disorders **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, lamotrigine, valproate **Dosage:** Mean daily dose: VPA (483.8 mg); CMZ (378.9 mg); LMG (78.4)
Outcomes	**Outcomes used:** Major congenital malformation **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	This study allows a comparison between women with epilepsy and women with psychiatric disorders taking anticonvulsants. Overall, the study found an increased rate of congenital malformations only in the cohort of the non-epileptic group compared to control group. No other outcomes could be used as data not disaggregated by individual drug

1.27.10 CHARLTON2011

Study ID	CHARLTON2011
Bibliographic reference	Charlton RA, Weil JG, Cunnington MC, Ray S, De Vries CS. Comparing the general practice research database and the UK epilepsy and pregnancy register as tools for postmarketing teratogen surveillance: anticonvulsants and the risk of major congenital malformations. Drug Safety. 2011;34:157-71
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical records **Country:** GB
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 1446 **N Exposed:** 634 **N Unexposed:** 902 **Mean age (years):** 30 **Diagnosis of exposed group:** Epilepsy

	Diagnosis of unexposed group: Epilsepsy **Inclusion criteria:** women were eligible for inclusion if they were, or had been, permanently registered at a GP practice considered by the GPRD division at the Medicines and Healthcare products Regulatory Agency (MHRA) to be contributing data up to standard for the purposes of researchFor live- and stillbirths (‡24 weeks' gestation) the pregnancy outcome date was considered to be the date of the first record of a pregnancy outcome when no additional records were identified in the preceding 90 days. For terminations of pregnancy, the date of the termination was taken as the last recorded termination of pregnancy code, within a 6-week window, as earlier termination of pregnancy codes commonly related to requests and referrals for an elective termination rather than the termination itself. **Exclusion criteria:** Pregnancy outcomes specifically stating that they were a spontaneousabortion or miscarriage; if the woman was not aged 14–49 years at the date of the pregnancy outcome and if she did not have any codes indicating a pregnancy (for example last menstrual period [LMP], pregnant, positive pregnancy test, antenatal care, etc.) in the 280 days before the pregnancy outcome data
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** caramazepine, lamotrigine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.11 CHRISTENSEN2013

Study ID	CHRISTENSEN2013
Bibliographic reference	Christensen J, Grnoborg TK, Sroensen MJ, Schendel D, Parner ET, Pedersen LH, et al. Prenatal valproate exposure and risk of autism spectrum disorders and childhood autism. Journal of the American Medical Association. 2013;309:1696-703
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** DK
Participants	**Trimester of exposure:** Any **Duration of exposure:** 30 days before estimated day of conception to the day of birth **Total N:** 655615 **N Exposed:** 508 **N Unexposed:** 655107 **Mean age (years):** 39% 26-30 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** NR **Inclusion criteria:** Women with exposure to valproate from 30 days before estimated day of conception to day of birth. Included children with estimated

	conception time after February 1, 1996 to December 31st, 2006. Children were defined as having been exposed to monotherapy if their mothers had filled prescriptions for only 1 type of antiepileptic drug and as exposed to polytherapy if their mothers had filled prescriptions for more than 1 type of antiepileptic drug. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Anticonvulsants (split by type) **Dosage:** NR
Outcomes	**Outcomes used:** Autism spectrum disorder **Outcomes not used:** N/A
Study design	Cohort
Source of funding	Dr Christensen receives research support from the Danish Epilepsy Association. Dr Pedersen is supported by a Sapere Aude–Postdoctoral grant from the Danish Council for Independent Research. This study was supported by grants from the European Research Cou
Limitations	
Notes	

1.27.12 DIAV-CITRIN2001

Study ID	DIAV-CITRIN2001
Bibliographic reference	Diav-Citrin O, Shechtman S, Arnon J, Ornoy A. Is carbamazepine teratogenic? A prospective controlled study of 210 pregnancies. Neurology. 2001;57:321-24
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview **Country:** IL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 420 **N Exposed:** 210 **N Unexposed:** 210 **Mean age (years):** 30 **Diagnosis:** Epilepsy 80.0%; trigeminal neuralgia or psychiatric disorder (nonepileptic) 12.9%; not specified, 7.1%. **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** The Israeli Teratogen Information Service advises medical professionals and women about possible teratogenic risks. The demographic and obstetric data with information on exposure are recorded at the time of initial contact. The callers concerning carbamazepine exposure in pregnancy between January 1989 and March 1999 were telephoned after the expected date of delivery. The data collection was according to a structured questionnaire. The results are based on the information provided by the women (87%) or their physicians. The control group included Israeli Teratogen Information Service callers about nonteratogenic exposures during pregnancy in the same time frame. Follow-up in the general control group was conducted

	using the same procedure as in the carbamazepine group and obtained for 629 (37.4%) of 1680 pregnancies. From this control group, women were matched (1:1) to the carbamazepine group by the year and the gestational and maternal age at time of call. An attempt was made to contact the treating physician for details and verification in every case of malformation. In all groups, follow-up was carried out within the first 2 years of life in most cases. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine **Dosage:** Mean daily dose of carbamazepine: 645 +/- 339 mg
Outcomes	**Outcomes used:** Major congenital malformations, still birth, birthweight, preterm birth **Outcomes not used:** Gestational age, miscarriage
Study design	Cohort
Source of funding	Supported by Grant 032-4056 from the Israeli Ministry of Commerce and Trade
Limitations	
Notes	Other outcomes could not be combined in meta-analysis

1.27.13 DIAV-CITRIN2008

Study ID	DIAV-CITRIN2008
Bibliographic reference	Diav-Citrin O, Shechtman S, Bar-Oz B, Cantrell D, Arnon J, Ornoy A. Pregnancy outcome after in utero exposure to valproate evidence of dose relationship in teratogenic effect. CNS Drugs. 2008;22:325-34.
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview **Country:** IL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** 34 **Total N:** 1469 **N Exposed:** 154 **N Unexposed:** 1315 **Mean age (years):** 30 **Diagnosis of exposed group:** 81.3% convulsive disorders, 18.7% other indications (psychiatric disorders or migraine) **Diagnosis of unexposed group:** General population **Inclusion criteria:** All women who contacted (directly or through their healthcare provider) the Israeli TIS between 1994 and 2004 for information about gestational exposure to valproate were enrolled in the study **Exclusion criteria:** Cases where an anomaly was prenatally diagnosed by the time of initial contact were not included in the study.
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Valporate **Dosage:** Median daily dose 600g.
Outcomes	**Outcomes used:** Major congenital malformations, birthweight, preterm birth, still birth **Outcomes not used:** N/A

Study design	Cohort
Source of funding	N/A
Limitations	
Notes	Contacted author for clarification on whether outcomes are still significant after controlling for confounders. Dosing is considered- no major malformations for <100 mg

1.27.14 DOLK2008

Study ID	DOLK2008
Bibliographic reference	Dolk H, Jentink J, Loane M, Morris J, de Jong-van den Berg LT. Does lamotrigine use in pregnancy increase orofacial cleft risk relative to other malformations? Neurology. 2008;71:714-22
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** Mixed
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 85563 **N Exposed:** 495 **N Unexposed:** 85068 **Mean age (years):** 29 **Diagnosis of exposed group:** Epilepsy (only 17 out of 495 had no record of maternal epilepsy) **Diagnosis of unexposed group:** **Inclusion criteria:** The EUROCAT central database holds individual standardized records of congenital anomaly registrations since 1980 including livebirths, stillbirths, and terminations of pregnancy following prenatal diagnosis. One syndrome and up to eight malformations are coded by ICD9 or ICD10 codes. Criteria for registries to participate in the study were: 1. Maternal epilepsy or antiepileptic drug exposure recorded for at least 3 per 1,000 registrations for the study period. This criterion was set a priori based on population information on epilepsy prevalence to exclude registries with low ascertainment of epilepsy. Specific drug name or complete seven-digit ATC code available for at least 80% of AED exposed babies/fetus for the study period **Exclusion criteria:** Babies with only anomalies on the EUROCAT list of minor anomalies10 are excluded
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Lamotrigine **Dosage:** NR
Outcomes	**Outcomes used:** Neural tube defects, clef-lip/palate **Outcomes not used:** Other individual malformations
Study design	Case-control
Source of funding	N/R
Limitations	
Notes	Only neural tube defects and cleft-lip/palate outcomes could be combined in a meta-analysis. Data not available to calculate overall major congenital

	malformations

1.27.15 ERIKSSON2005

Study ID	ERIKSSON2005
Bibliographic reference	Eriksson K, Viinikainen K, Monkkonen A, Aikia M, Nieminen P, Heinonen S, et al. Children exposed to valproate in utero--population based evaluation of risks and confounding factors for long-term neurocognitive development. Epilepsy Research. 2005;65:189-200
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Clinical assessment **Country:** FI
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 39 **N Exposed:** 26 (13 carbamazepine; 13 valproate) **N Unexposed:** 13 **Mean age (years):** 28 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Study population was identified through a prospective community-based pregnancy registry covering the whole catchment area of the Kuopio University Hospital (population 250,000 inhabitants) in Finland and includes women with epilepsy who had given birth between January 1989 and October 2000. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Full scale IQ, verbal IQ, performance IQ **Outcomes not used:** EEPSY subscales
Study design	Cohort
Source of funding	Paivikki and Sakari Sohlberg Foundation and funded mainly from internal departmental funds and resources of the Neurological Department of Kuopio University Hospital.
Limitations	
Notes	Only IQ outcomes could be combine in a meta-analysis

1.27.16 GAILY2004/ KANTOLA-SORSA2007

Study ID	GAILY2004/KANTOLA-SORSA2007
Bibliographic reference	Gaily E, Kantola-Sorsa E, Hiilesmaa V, Isoaho M, Matila R, Kotila M, et al. Normal intelligence in children with prenatal exposure to carbamazepine. Neurology. 2004;62:28-32
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Obstetric database **Country:** FI

Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 144 **N Exposed:** 99 (carbamazepine 86; valproate 13) **N Unexposed:** 45 (epileptic mothers) **Mean age (years):** Mean age of children=7 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Liveborn children born at Helsinki University Hospital 1989-1994to mothers with a history of seizures or epilepsy were enrolled in this study. The next child born at the same hospital to a nonepileptic mother with similar socioeconomic class (defined as the mother's educational level), age (2 years), and parity was chosen as the control subject for the first included child of every mother with epilepsy. All siblings of the selected control children were also enrolled as control subjects, provided that they were born at the same hospital. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** Median (range) CBZ = 60 (100-900) VPA = 1200 (600-2400)
Outcomes	**Outcomes used:** Full scale IQ, verbal IQ, performance IQ **Outcomes not used:** NEPSYscores
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	NEPSY scores not extracted as only some subscales have been reported, no overall mean given. Therefore possible reportig bias.

1.27.17 HERNANDEZ-DIAZ2012

Study ID	HERNANDEZ-DIAZ2012
Bibliographic reference	Hernandez-Diaz S, Smith CR, Shen A, Mittendorf R, Hauser WA, Yerby M, et al. Comparative safety of antiepileptic drugs during pregnancy. Neurology. 2012:78;1692-1699.
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** US
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 3360 **N Exposed:** 2918 (lamotrigine=1562; carbamazepine=1033; valproate=323) **N Unexposed:** 442 **Mean age (years):** 30 **Diagnosis of exposed group:** Epilepsy (92%), mood disorders (6%), migraine (1%), and other conditions **Diagnosis of unexposed group:** General population **Inclusion criteria:** Women self-enrolled by calling a toll-free telephone number. To be eligible, a woman must be pregnant and have taken AEDs at some point during her pregnancy.Women were eligible for analysis if they had

	a liveborn infant, a stillborn infant, or a pregnancy terminated because of a fetal abnormality. The units of analysis were pregnancies, and malformations in one or more fetuses in twins were considered as one outcome. **Exclusion criteria:** ineligible if they had a spontaneous abortion, withdrew from the Registry, or were lost to follow-up.
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, lamotrigine, valproate **Dosage:** The median average daily dose during the first trimester was 1,000 mg for pregnancies with malformations and 750 mg for those without malformations- for valproate
Outcomes	**Outcomes used:** Major congenital malformation, neural tube defect **Outcomes not used:** Other isolated malformations
Study design	Cohort
Source of funding	Dr. Herna´ndez-Díaz received salary support from funds provided by sponsors of the North American AED Pregnancy Registry: Abbott, Eisai, Novartis, Ortho-McNeil, Pfizer, and Sunovion Pharmaceuticals. C.R. Smith received salary support from funds provided b
Limitations	
Notes	Other isolated malformations could not be combined in meta-analysis

1.27.18 HOLMES2001

Study ID	HOLMES2001
Bibliographic reference	Holmes LB. Looking for long-term effects from prenatal exposures to anticonvulsants. Teratology. 2001;64:175-76
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview **Country:** US
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 321 **N Exposed:** 223 **N Unexposed:** 98 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** History of seizures **Inclusion criteria:** Potential subjects were identified in the labor and delivery suites by nurses who asked the women if they had taken any medication for seizures during the pregnancy and if they had ever had a seizure. Women who answered yes to either question were then interviewed, with the approval of their obstetricians and nurses, to inform them about the study and to determine whether they qualified for inclusion **Exclusion criteria:** Women were excluded if they did not speak English, had a multiple-gestation pregnancy, or had another potentially teratogenic factor, such as type 1 diabetes mellitus.
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine **Dosage:** NR

Outcomes	**Outcomes used:** Major congenital malformations, congenital malformations, cleft lip/palate **Outcomes not used:** Other individual isolated malformations
Study design	Cohort
Source of funding	Supported by a grant (NS 24125) from the National Institutes of Health.
Limitations	
Notes	Other isolated malformations could not be combined in meta-analysis Dat for cleft lip/palate have been combined with HOLMES2008 (see below) as they used the same comparison group

1.27.19 HOLMES2008

Study ID	HOLMES2008
Bibliographic reference	Holmes L, Baldwin E, Smith C, Habecker E, Glassman L, Wong S. Increased frequency of isolated cleft palate in infants exposed to lamotrigine during pregnancy. Neurology. 2008:70;2152-2158
Methods	**Prospective/Retrospective:** Prospective cohort **Data collection:** Registries **Country:** US
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 206908 **N Exposed:** 684 **N Unexposed:** 206224 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Only women exposed to an anticonvulsant drug as monotherapy during the first 16 weeks of gestation were analyzed. Monotherapy was defined as exposure to only one anticonvulsant drug at any time during pregnancy. If a second anticonvulsant drug was added after 16 weeks of gestation, that woman's pregnancy was considered monotherapy exposed. Unexposed women were those surveyed at Brigham and womens hospital- the same inclusion/exclusion criteria were used. prevalence was obtained between 1972 and 1984 and between 1979 and 2000. Since the time period for identification of major malformations in the comparion group was between birth and 5 dats of age, the time period for the identification of mlformations in the LGT-exposed group was limited to birth to 5 days of age. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine**,** Lamotrigine, Valproate **Dosage:** 344.7 mg for 19 mothers with malformed infants and 319.3 mg for the 665 mothers whose infants were not malformed
Outcomes	**Outcomes used:** Cleft lip/palate **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	

Notes	

1.27.20 HVAS2000

Study ID	HVAS2000
Bibliographic reference	Hvas CL, Henriksen TB, Ostergaard JR, Dam M. Epilepsy and pregnancy: effect of antiepileptic drugs and lifestyle on birthweight. British Journal of Obstetrics and Gynaecology. 2000;107:896-902
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Questionnaire **Country:** DK
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 193 **N Exposed:** 87 **N Unexposed:** 106 (epilepsy) **Mean age (years):** unclear **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** All Danish-speaking women who attended for antenatal care at Aarhus University Hospital from July 1989 to January 1997 were asked to complete a questionnaire regarding medical and obstetric history, lifestyle, and social factors. **Exclusion criteria:** All women who reported chronic disease other than epilepsy were excluded from the study. Further restriction was made to singleton pregnancies with known sex and birthweight of the child
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Birthweight **Outcomes not used:**
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	Only for birthweight was data disaggregated for invididual anticonvulsant

1.27.21 JENTINK2010

Study ID	JENTINK2010
Bibliographic reference	Jentink J, Loane MA, Dolk H, Barisic I, Garne E, Morris JK, et al. Valproic acid monotherapy in pregnancy and major congenital malformations. New England Journal of Medicine. 2010;362:2185-93
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** Mixed
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported

	Total N: Unclear **N Exposed:** 121 **N Unexposed:** Unclear **Mean age (years):** NR **Diagnosis of exposed group:** NR **Diagnosis of unexposed group:** Unclear **Inclusion criteria:** EUROCAT Antiepileptic Study Database.drawn from 19 population based registries of congenital anomaly in Europe, covering 3 881 592 births in Europe in 1995- 2005 and 98 075 major congenital malformations: 86 291 non-chromosomal and 11 784 chromosomal. Information was available for live births, still births or late fetal deaths from 20 weeks' gestation, and terminations of pregnancy after prenatal diagnosis **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:**
Study design	Case-control
Source of funding	N/R
Limitations	
Notes	Data taken from the case-control study

1.27.22 KAAJA2003

Study ID	KAAJA2003
Bibliographic reference	Kaaja E, Kaaja R, Hiilesmaa V. Major malformations in offspring of women with epilepsy. Neurology. 2003;60:575-79
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Hospitals **Country:** FI
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 663 **N Exposed:** 363 CBZ, 61 VPA **N Unexposed:** 239 **Mean age (years):** 29 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Between January 1980 and September 1998, a total of 988 pregnant women with established epilepsy diagnosed before pregnancy were referred for follow-up to the Department of Obstetrics and Gynecology of Helsinki University Central HospitalWe enrolled all women with epilepsy regardless of whether they used AED during the index pregnancy. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations

	Outcomes not used: N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.23 KANEKO1999

Study ID	KANEKO1999
Bibliographic reference	Kaneko S, Battino D, Andermann E, Wada K, Kan R, Takeda A, et al. Congenital malformations due to antiepileptic drugs. Epilepsy Research. 1999;33:145-58
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** Mixed
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 337 **N Exposed:** 158/81 (CZ/VP monotherapy) **N Unexposed:** 98 **Mean age (years):** 27 **Diagnosisof exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Recruitment of subjects began in April 1978, and was completed in December 1991. At each center, where the study was introduced, the nature and purpose of the study was explained to every female patient of childbearing age with epilepsy who visited the clinic. Those who consented were followed by a team of obstetricians and neurologists at a minimum of monthly intervals throughout their pregnancy. Most of our subjects have been studied from the first trimester of pregnancy, and a few subjects were studied before conception. The population of the study group was composed of women with different socio-cultural backgrounds, mainly from the suburban areas around each medical center. **Exclusion criteria:** Mothers who did not follow up as scheduled
Interventions	MOLGAARD-NIELSEN2011
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.24 KINI2007

Study ID	KINI2007
Bibliographic reference	Kini U, Lee R, Jones A, Smith S, Ramsden S, Fryer A, et al. Influence of the

	MTHFR genotype on the rate of malformations following exposure to antiepileptic drugs in utero. European Journal of Medical Genetics. 2007;50:411-20
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Clinical assessment **Country:** GB
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 77 **N Exposed:** 38 CBZ, 40 VPA **N Unexposed:** 34 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Women with epilepsy recruited by research nurses at the time of booking for antenatal care from 4 centres in the Manchester area and 7 centres in the Cheshire and Merseyside regions of the UK. Control mothers were matched for socio-economic status (via postcode), age and parity were reruited at the same time. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.25 MOLGAARD-NIELSEN2011

Study ID	MOLGAARD-NIELSEN2011
Bibliographic reference	Molgaard-Nielsen D, Hviid A. Newer-generation antiepileptic drugs and the risk of major birth defects. Obstetrical and Gynecological Survey. 2011;66:543-44
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** DK
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 837795 **N Exposed:** 1532 **N Unexposed:** 836 263 **Mean age (years):** 45% 25-29, 36% 30-34 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** General population **Inclusion criteria:** The Medical Birth Registry was established in 1978 and

	contains records onall Danish births. The records include the personal identification number (a 10-digit number assigned to all Danish residents) of the parents and the newborn, date of birth, indication of single vs multiple births, gestational age, vital status, and other physical characteristics of the newborn. We constructed a study cohort of all live births from January 1, 1996, through September 30, 2008, using the Medical Birth Registry. The onset of pregnancy was defined as the first day of the last menstrual period and was estimated by subtraction of the gestational age from the date of birth.We included the following types of prescriptions filled by the cohort mothers from the first day of the last menstrual period until birth **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Lamotrigine **Dosage:** Mixed
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** Individual malformations
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	Individual malformations could not me mata-anaysed

1.27.26 MORROW2006

Study ID	MORROW2006
Bibliographic reference	Morrow J, Russell A, Guthrie E, Parsons L, Robertson I, Waddell R, et al. Malformation risks of antiepileptic drugs in pregnancy: a prospective study from the UK Epilepsy and Pregnancy Register. Journal of Neurology, Neurosurgery and Psychiatry. 2006;77:193-98
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** GB
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 3607 **N Exposed:** 3368 **N Unexposed:** 239 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Pregnant women with epilepsy, whether or not they were taking an AED, either in monotherapy or polytherapy, and who were referred to the register before the outcome of the pregnancywas known. Cases with exposure to more than one AED during the first trimester, or who had additional AEDs starting in the second or third trimesters, were counted as polytherapy exposures. **Exclusion criteria:** Cases where any prenatal test (fetal ultrasound, blood test) had shown an abnormality, and cases resulting in a pregnancy loss in which an abnormality had been identified before referral to the register had been made. Cases that were on no AEDs during the first trimester but then had second or

	third trimester exposure to an AED
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, lamotrigine, valproate **Dosage:** Mixed doses
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	The study was made possible by a research grant from the Epilepsy Research Foundation and a number of educational grants from pharmaceutical companies (Glaxo-Smith-Kline, Sanofi-Aventis, UCB-Phama, Janssen-Cilag, Pfizer.) An internet based web site detail
Limitations	
Notes	

1.27.27 ORNOY1996

Study ID	ORNOY1996
Bibliographic reference	Ornoy A, Cohen E. Outcome of children born to epileptic mothers treated with carbamazepine during pregnancy. Archives of disease in childhood. 1996;75:517-20
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Face-to-face interview **Country:** IL
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** 94 **N Exposed:** 47 **N Unexposed:** 47 **Mean age (years):** Children 6m-6yrs **Diagnosis of the exposed group:** Epilepsy **Diagnosis unexposed group:** General population **Inclusion criteria:** Women with epilepsy who were treated with carbamazepine alone, or in combination with other anticonvulsants. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine **Dosage:** CBZ = 658 (329) mg, with a range of 200-1800 mg/day.
Outcomes	**Outcomes used:** Major congenital malformations, Full scale IQ **Outcomes not used:** Mental development, motor development
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	Mental and motor development could not be combined in meta-analysis

1.27.28 RIHTMAN2013

Study ID	RIHTMAN2013
Bibliographic reference	Rihtman T, Parush S, Ornoy A. Developmental outcomes at preschool age after fetal exposure to valproic acid and lamotrigine: Cognitive, motor, sensory and behavioral function. Reproductive Toxicology. 2013;41:115-25
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Questionnaire **Country:** IS
Participants	**Trimester of exposure:** At least 1st trimester **Duration of exposure:** Not reported **Total N:** 124 **N Exposed:** 72 **N Unexposed:** 52 **Mean age (years):** 34 **Diagnosis of exposed group:** NR **Diagnosis of unexposed group:** NR **Inclusion criteria:** Fluency in Hebrew (child and parents) (all groups) and exposure to VPA or LT monotherapy for a minimum of the first trimester of pregnancy (AED-exposed groups). **Exclusion criteria:** Exclusion criteria (all groups) were genetic abnormalities and full scale IQ of less than 70; it is important to note that this criterion was selected during the study design phase in order to prevent potentially skewed results yet in the final analyses, no children were excluded for this reason
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Lamotrigine, valproate **Dosage:** Mean valproate dose: 546.3 mg, mean lamotrigine dose: 293.3 mg
Outcomes	**Outcomes used:** Full scale IQ, verbal IQ, performance IQ **Outcomes not used:** Other neurodevelopmental outcomes
Study design	Cohort
Source of funding	Martin and Vivian Levin Center for the Normal and Psychopathological Development of the Child and Adolescent, the Israel Association for Child Development and Rehabilitation and the Rama Shoval-Etial Fund.
Limitations	
Notes	Other neurodevelopmental outcomes could not be combined in meta-analysis

1.27.29 RODRGIGUEZ-PINILLA2000

Study ID	RODRIGUEZ-PINILLA2000
Bibliographic reference	Rodriguez-Pinilla E, Arroyo I, Fondevilla J, Garcia MJ, Martinez-Frias ML. Prenatal exposure to valproic acid during pregnancy and limb deficiencies: a case-control study. American Journal of Medical Genetics. 2000;90:376-81
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Hospitals **Country:** ES
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 44241

	N Exposed: 67 **N Unexposed:** 44174 **Mean age (years):** NR **Diagnosis of exposed group:** NR **Diagnosis of unexposed group:** NR **Inclusion criteria:** Data from ECEMC (hospital-based case-control study and surveillance system). **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Valporate **Dosage:** NR
Outcomes	**Outcomes used:** Congenital malformaion **Outcomes not used:** N/A
Study design	Case-control
Source of funding	N/R
Limitations	
Notes	

1.27.30 SAMREN1999

Study ID	SAMREN1999
Bibliographic reference	Samren EB, Van Duijn CM, Christiaens GCML, Hofman A, Lindhout D. Antiepileptic drug regimens and major congenital abnormalities in the offspring. Annals of Neurology. 1999;46:739-46
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Hospitals **Country:** NL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 3411 **N Exposed:** 1411 **N Unexposed:** 2000 **Mean age (years):** 41% 25-29 **Diagnosis of exposed group:** NR **Diagnosis of unexposed group:** General population **Inclusion criteria:** Women with epilepsy,women were using antiepileptic drugs at least during the first trimester of pregnancy. matched nonexposed controls and children born to these women were included in the study. Control pregnancies were matched to the cases for age and parity of the mother, and sex, birth year, and hospital of delivery of the child **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Valporate, carbamazepine **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort

Source of funding	Commissie Landelijk Epilepsie Onderzoek (CLEO) of the National Epilepsy Fund (CLEO/NEF A-90).
Limitations	
Notes	

1.27.31 STEEGERS-THEUNISSEN1994

Study ID	STEEGERS-THEUNISSEN1994
Bibliographic reference	Steegers-Theunissen RPM, Renier WO, Borm GF, Thomas CMG, Merkus HMWM, Op De Coul DAW, et al. Factors influencing the risk of abnormal pregnancy outcome in epileptic women: A multi-centre prospective study. Epilepsy Research. 1994;18:261-69
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Hospitals **Country:** NL
Participants	**Trimester of exposure:** NR **Duration of exposure:** NR **Total N:** 119 **N Exposed:** 99 **N Unexposed:** 20 **Mean age (years):** 29 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** The study was conducted at five centres in the Netherlands: two university hospitals (of Amsterdam and of Nijmegen), and three general hospitals (Maria and Elisabeth hospital, Tilburg and Catharina hospital, Eindhoven). The protocol was approved by the Medical Ethical Committees of these hospitals. Epileptic and healthy control women were recruited before conception. They could only participate if they or any first-degree relative had no genetic disorder known to cause major congenital malformations, and if they were not under treatment for infectious, metabolic, endocrine or malignant diseases. In all epileptic women the onset of epilepsy had to be prior to the pregnancy. The diagnosis of the epilepsy and the types of seizures had to be confirmed by a neurologist. To avoid bias and unreliable error rates, we studied just one singleton pregnancy per woman. **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.32 VAJDA2007

Study ID	VAJDA2007
Bibliographic reference	Vajda FJE, Hitchcock A, Graham J, O'Brien T, Lander C, Eadie M. The Australian Register of Antiepileptic Drugs in Pregnancy: the first 1002 pregnancies. Australian and New Zealand Journal of Obstetrics and Gynaecology. 2007;47:468-74
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** AU
Participants	**Trimester of exposure:** At least 1st trimester **Duration of exposure:** Not reported **Total N:** **N Exposed:** 546 (234 CBZ; 146 LMG; 166 VPA) **N Unexposed:** 83 **Mean age (years):** 31 **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** There were three patterns of enrolment, namely, (i) truly prospective – those who had no tests for fetal abnormality performed by the time of enrolment usually less than 12 weeks gestation; (ii) prospective – those who have had screening tests for fetal abnormalities done prior to enrolment, but have not yet delivered; and (iii) retrospective – women who have reached any known outcome by the time they enrolled.Of the 992 pregnancies analysed, 958 (96.6%) were in WWE. Of the 958, eighty-three (8.4% of the original 992 pregnancies) were not exposed to AEDs in at least the first trimester, though by the time pregnancies were completed, 36 of the 83 had resumed AED exposure. Hence, there were 875 pregnancies exposed to AEDs throughout pregnancy. There were 34 pregnancies in women without epilepsy, that is, those suffering from psychiatric or pain syndromes, who were exposed to AEDs (3.4% of the series). **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine Lamotrigine Valproate **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations **Outcomes not used:** N/A
Study design	Cohort
Source of funding	National Health and Medical Research Council
Limitations	
Notes	

1.27.33 VEIBY2013

Study ID	VEIBY2013
Bibliographic reference	Veiby G, Daltveit AK, Schjolberg S, Stoltenberg C, Oyen AS, Vollset SE, et al. Exposure to antiepileptic drugs in utero and child development: a prospective

	population-based study. Epilepsia. 2013;54:1462-72
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Hospitals **Country:** NO
Participants	**Trimester of exposure:** Any **Duration of exposure:** Not reported **Total N:** **N Exposed:** 333 **N Unexposed:** 393 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** The target population was women who gave birth in Norway, recruited from hospitals and maternity units. Women attending free routine ultrasound scanning (>98%of pregnant women in Norway) were invited to participate. Included in the analysis are mothers with AED exposure and those with no AED exposure **Exclusion criteria:** NR
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** carbamazepine, lamotrigine, valproate **Dosage:** NR
Outcomes	**Outcomes used:** Autism checklist **Outcomes not used:**
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.27.34 WERLER2011

Study ID	WERLER2011
Bibliographic reference	Werler MM, Ahrens KA, Bosco JLF, Mitchell AA, Anderka MT, Gilboa SM, et al. Use of Antiepileptic Medications in Pregnancy in Relation to Risks of Birth Defects. Annals of Epidemiology. 2011;21:842-50
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Telephone interview **Country:** US
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 8554 **N Exposed:** 26 **N Unexposed:** 8528 **Mean age (years):** NR **Diagnosis of exposed group:** Epilepsy **Diagnosis of unexposed group:** Epilepsy **Inclusion criteria:** Eligible cases include pregnancies affected with any of 30 major structural malformations but without known chromosomal or single-

	gene disorders. Control subjects were infants without any known birth defects selected from births at hospitals where cases were ascertained or by random sample of births in the case catchment areas. **Exclusion criteria:** Women who reported a history of seizures but no diagnosis of epilepsy or AED use most likely experienced childhood febrile seizures only (n Z 534) were excluded from analyses. In addition, women whose seizure history was unknown or missing (n Z 25) or who reported seizure, but not epilepsy history, and used AEDs before or after the first trimester (n Z 14) were excluded.
Interventions	**Drug class:** Anticonvulsants **Drug/s examined:** Carbamazepine Lamotrigine Valproate **Dosage:** NR
Outcomes	**Outcomes used:** Cleft lip and/or palate **Outcomes not used:** Other individual malformations
Study design	Case-control
Source of funding	Funding came from a cooperative agreement from Centers for Disease Control and Prevention
Limitations	
Notes	Other individual malformations could not be combined in meta-analysis

1.28 ANTICONVULSANTS – EXCLUDED STUDIES

Study	Reason for exclusion
Adab N, Jacoby A, Smith D, Chadwick D. Additional educational needs in children born to mothers with epilepsy. Journal of Neurology Neurosurgery and Psychiatry. 2001:70;15-21	Unable to combine outcomes (additional eucational needs in meta-analysis)
Almgren M, Kallen B, Lavebratt C. Population-based study of antiepileptic drug exposure in utero-Influence on head circumference in newborns. Seizure. 2009;18:672-75	Head circumference data not extractable- SDS reported. Have extracted adjusted odds ratios for dichotomous data (no raw figures provided)
Artama M, Ritvanen A, Gissler M, Isojrvi J, Auvinen A. (2006). Congenital structural anomalies in offspring of women with epilepsy – A population-based cohort study in Finland. International Journal of Epidemiology. 2006;35:280-287	No information on maternal use of antiepileptic or any other medication.
Arulmozhi T, Dhanaraj M, Rangaraj R, Vengatesan A. Physical growth and psychomotor development of infants exposed to antiepileptic drugs in utero. Neurology India. 2006;54:42-46	60% of patients on Phenytoin- does not disaggregate data for drugs of interest
Bertollini, R, Kallen B, Mastroiacovo P, Robert E.Anticonvulsant drugs in monotherapy. Effect on the fetus. European journal of epidemiology. 1987;3:164-171.	Data not extractable
Bromley RL, Mawer GE, Briggs M, Cheyne C, Clayton-Smith J, Garcia-Finana M, et al. The prevalence of neurodevelopmental disorders in children prenatally exposed to antiepileptic drugs. Journal of Neurology, Neurosurgery and Psychiatry. 2013:84;637-643	Data for ASD, ADHD or dyspraxia could not be combined in meta-analysis
Campbell E, Kennedy F, Russell A, Smithson WH, Parsons L, Morrison PJ. Malformation risk of antiepileptic drug monotherapies in pregnancy: updated results from the UK and Ireland Epilepsy and Pregnancy Registers. Neurol Neurosurg Psychiatry 2014;0:1–6.	No unexposed comparison group
Cunnington MC, Weil JG, Messenheimer JA, Ferber S, Yerby M, Tennis P. Final results from 18 years of the International Lamotrigine Pregnancy Registry. Neurology. 2011:76;1817-1823	No unexposed control group
Ebbesen F, Holsteen V, Rix M, Moeller M, Joergensen A, Hoseth E. Neonatal hypoglycaemia and withdrawal symptoms after exposure in utero to valproate. Archives of Disease in Childhood: Fetal and Neonatal Edition. 2000;83:F124-F129.	No control group
Fonager K, Larsen H, Pedersen L, Sorensen HT. Birth outcomes in women exposed to anticonvulsant drugs. Acta Neurologica Scandinavica. 2000:101;289-294	Does not disaggregagte data by individual anticonvulsant
Forsberg L, Wide K, Kallen B. School performance at age 16 in children exposed to antiepileptic drugs in utero-A population-based study. Epilepsia. 2011;364-369	Outcomes could not be combined in meta-analysis (not passed in school subjects)
Jager-Roman E, Deichl A, Jakob S. Fetal growth, major malformations, and minor anomalies in infants born to women receiving valproic acid. Journal of Pediatrics. 1986;108:997-1004	No unexposed control group (Valproate- focus of the study and participants recruited to compare monotherapy to combination therapy (no indication of which drugs constituted combination therapy)

Jentink J, Dolk H, Loane MA, Morris JK, Wellesley D, Game E. Intrauterine exposure to carbamazepine and specific congenital malformations: sysytematic review and case-control study. British Medical Journal. 2010;341:c6581	No raw event data for unexposed control group within the case-control study
Kaaja E, Kaaja R, Matila R, Hiilesmaa V. Enzyme-inducing antiepileptic drugs in pregnancy and the risk of bleeding in the neonate. Neurology. 2002;53:549-553	Outcome not able to use in meta-analysis (bleeding complication)
Koch S, Titze K, Zimmermann RB, Schroder M, Lehmkuhl U, Rauh H. Long-term neuropsychological consequences of maternal epilepsy and anticonvulsant treatment during pregnancy for school-age children and adolescents. Epilepsia. 1999;40:1237-1243.	Does not distinguish between different AEDs
Kroes HY, Reefhuis J, Cornel MC. Is there an association between maternal carbamazepine use during pregnancy and eye malformations in the child? Epilepsia. 2002;43:929-931	Not an individual cohort study
Kulaga S, Sheehy O, Zargarzadeh AH, Moussally K, Berard A. Antiepileptic drug use during pregnancy: Peruinatal outcomnes. Seizure. 2011;20:667-672	Did not disaggregate data by individual anticonvulsant
Lakshmi S and Sunanda KS. Effect of anti-epileptic drugs in pregnancy and teratogenesis. Indian Journal of Clinical Biochemistry. 2008;23:267-271	only 30 exposed- of that only 14 (47% on CMZ). 53% not medication of interest
Lin HL, Chen YH, Lin HC, Lin HC. No increase in adverse pregnancy outcomes for women receiving antiepileptic drugs. Journal of neurology. 2009:256;1742-1749	Does not disaggreate data by individual drug
Lindhout D, Omtzigt JGC. Pregnancy and the risk of teratogenicity. Epilepsia. 1992;33:not reported	No control group
Mawhinney E, Campbell J, Craig J, Russell A, Smithson W, Parsons L. et al. Valproate and the risk for congenital malformations: Is formulation and dosage regime important? Seizure. 2012;21:215-218	No unexposed control group
McVearry KM, Gaillard WD. VanMeter J, Meador KJ. A prospective study of cognitive fluency and originality in children exposed in utero to carbamazepine, lamotrigine, or valproate monotherapy. Epilepsy and Behavior. 2009;16:609-616	No unexposed control group
Meador K, Baker G, Browning N, Cohen M, Bromley R, Clayton-Smith J. Effects of fetal antiepileptic drug exposure: Outcomes at age 4.5 years. Neurology. 2012;78:1207-1214	No unexposed control group
Miskov S, Gjergja Juraski R, Fucic A, Bosnjak-Pasic M, Ivicevic-Bakulic T, Cvitanovic-Sojat L. Prospective surveillance of croatian pregnant women on lamotrigine monotherapy – Aspects of pre-pregnancy counseling and drug monitoring. Acta Clinica Croatica. 2009;48:271-281	No unexposed control group
Nadebaum C, Anderson VA, Vajda F, Reutens DC, Barton S, Wood AG. Language skills of school-aged children prenatally exposed to antiepileptic drugs. Neurology. 2011;76:719-726.	No unexposed control group
Nakane Y, Okuma T, Takahashi R. Multi-institutional study on the teratogenicity and fetal toxicity of antiepileptic drugs: a report of a collaborative study group in Japan. Epilepsia. 1980;21:663-680.	Data not extractable
Nau H, Rating D, Koch S. Valproic acid and its metabolites: Placental transfer, neonatal pharmacokinetics, transfer via mother's milk and clinical status in neonates of epileptic mothers. Journal of Pharmacology and Experimental Therapeutics.	Only 12 per arm. Aim of the study outside scope

1981;219:768-777.	
Nulman I, Rovet J, Stewart DE, Wolpin J, Gardner HA, Theis JGW, et al. Neurodevelopment of children exposed in utero to antidepressant drugs. New England Journal of Medicine. 1997;336:258-62	Does not disaggreate data by individual drug
Omtzigt JG, Los FJ, Grobbee DE, Pijpers L, Jahoda MG, Brandenburg H. The risk of spina bifida aperta after first-trimester exposure to valproate in a prenatal cohort. Neurology. 1992;42:119-125	No control group
Pennell PB, Klein AM, Baker GA, Kalayjian L A, Liporace JD, Loring DW. Differential effects of antiepileptic drugs on neonatal outcomes. Epilepsy and Behavior. 2012;24:449-456.	No unexposed control group
Rodriguez-Pinilla E, Mejias C, Prieto-Merino D, Fernandez P, Martinez-Frias ML. Risk of hypospadias in newborn infants exposed to valproic acid during the first trimester of pregnancy: a case-control study in Spain. Drug Safety. 2008;31:537-43	Single study outcome (hypospadis)
Rosa FW. Spina bifida in infants of women treated with carbamazepine during pregnancy. New England Journal of Medicine. 1991;324:674-677	No unexposed control group
Samren EB, Van Duijn CM, Koch S, Hiilesmaa VK, Klepel H, Bardy AH. Maternal use of antiepileptic drugs and the risk of major congenital malformations: A joint European prospective study of human teratogenesis associated with maternal epilepsy. Epilepsia. 1997;38:981-990	No control group available for 3 of the cohorts- studies included previously exlucded (ie Koch-supplement). No extractable data
Tanganelli P and Regesta G. Epilepsy, pregnancy, and major birth anomalies: an Italian prospective, controlled study. Neurology. 1992;42(4 Suppl 5):89-93.	Data not available
Tennis P, Eldridge RR, Cragan J, Holmes L, Lieberman E, Messenheimer, J, et al. Preliminary results on pregnancy outcomes in women using lamotrigine. Epilepsia. 2002;43:1161-1167	No unexposed control group (compared lamotrigine monotherapy with polypharmacy)
Thomas SV, Ajaykumar B, Sindhu K, Nair MKC, George B, Sarma PS. Motor and mental development of infants exposed to antiepileptic drugs in utero. Epilepsy and Behavior. 2008;13:229-36	Mental and motor development scores cannot be combined in meta-analysis
Vajda F, O'Brien TJ, et al. Critical relationship between sodium valproate dose and human teratogenicity: Results of the Australian register of anti-epileptic drugs in pregnancy. Journal of Clinical Neuroscience. 2004;11:854-858.	Definition of outcome unclear
Wide K, Winbladh B, Tomson T, Kallen B. Body dimensions of infants exposed to antiepileptic drugs in utero: Observations spanning 25 years. Epilepsia. 2000;41: 854-861	Outcomes not extractable- no absolute rates provided
Wyszynski DF, Nambisan M, Surve T, Alsdorf RM, Smith CR, Holmes LB, et al. Increased rate of major malformations in offspring exposed to valproate during pregnancy. Neurology. 2005;64:961-965.	No unexposed control group- valproate is compared to all other AED. Other comparison groups not applicable

1.29 BENZODIAZEPINES – INCLUDED STUDIES

1.29.1 BAN2014

Study ID	BAN2014
Bibliographic reference	Ban L, West J, Gibson JE, Fiaschi L, Sokal R, Doyle P, et al. First Trimester Exposure to Anxiolytic and Hypnotic Drugs and the Risks of Major Congenital Anomalies: A United Kingdon Popluation-Based Cohort Study. PLoS ONE. 2014;9:e100996
Methods	**Prospective/Retrospective:** Prospective **Data collection:** database of computerised 84 longitudinal general practice records of prospectively-collected health information across the UK **Country**: UK
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 21137 **N Exposed:** 1944 **N Unexposed:** 19193 **Mean age (years):** 29 (median) **Diagnosis:** depression and/or anxiety **Inclusion criteria:** We used a pregnancy cohort study design which included all singleton live births for women aged 15-81 45 years between 1990 and 2010 from The Health Improvement Network (THIN), where anonymised 82 children's and mothers' medical records were linked to provide prospectively recorded information 83 before, during and after pregnancy **Exclusion criteria:** women with serious mental illness (that is, bipolar disorder, schizophrenia and other related 103 psychotic disorders) and women with epilepsy diagnoses or with prescriptions of antiepileptic drugs in 104 pregnancy (4,739 pregnancies/1.2% of the total population) since previous literature has shown 105 increases of congenital anomalies in children born to women treated for such conditions.
Interventions	**Drug class:** Benzodiazepines **Drug/s examined:** Diazepan, temazepam, zopiclone **Dosage:** NR
Outcomes	**Outcomes used:** Major congenital malformations, cardiac abnormalities, cleft lip/palate **Outcomes not used:** Other individual malformations
Study design	Cohort
Source of funding	NR
Limitations	
Notes	Used disordered comparison group

1.29.2 CZEIZEL1987

Study ID	CZEIZEL1987
Bibliographic reference	Czeizel A. Lack of evidence of teratogenicity of benzodiazepine drugs in Hungary. Reproductive toxicology. 1987;1:183-88
Methods	**Prospective/Retrospective:** Retrospective

	Data collection: Medical records and self report questionnaire **Country:** Hungary
Participants	**Trimester of exposure:** Any **Duration of exposure:** NR **Total N:** 2402 **N Exposed:** 228 **N Unexposed:** 2174 **Mean age (years):** NR **Diagnosis: NR** **Inclusion criteria:** Study sample involved index cases with facial clefting born in the years 1970-1976 and registered in the Hungarian Congenital Malformation Register (HCMR). Using the records of the obstetrical institutions where index cases were born, three controls were matched to each index case by birth place, week of birth, sex and outcome **Exclusion criteria:** NR
Interventions	**Drug class:** Benzodiazepines **Drug/s examined:** Chlordiazepoxide, diazepam and nitrazepam. **Dosage:** NR
Outcomes	**Outcomes used:** Cleft lip/palate **Outcomes not used:** Multiple congenital malformations
Study design	Case-control
Source of funding	NR
Limitations	
Notes	Non exposed = not exposed to comparison drug (not clear whether participants were exposed to other benzodiazepines)

1.29.3 LAEGREID1990

Study ID	LAEGREID1990
Bibliographic reference	Laegreid L, Olegard R, Conradi N, Hagberg G, Wahlstrom J, Abrahamsson L. Congenital malformations and maternal consumption of benzodiazepines: a case-control study. Developmental Medicine & Child Neurology. 1990;32:432-41 Laegreid L. Clinical observations in children after prenatal benzodiazepine exposure. Developmental Pharmacology and Therapeutics. 1990:15;186-188
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Medical records **Country:** Sweeden
Participants	**Trimester of exposure:** NR **Duration of exposure:** NR **Total N:** 78 (N for whom blood samples to determine exposure were available) **N Exposed:** 10 **N Unexposed:** 68 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** The diagnostic register at the East Hospital and the files of dead neonates were reviewed. 25 children were identified as born alive in the

	study period with one or more of the selected diagnoses (Malformations were: embryopathy and fetopathy, unspecified; unspecified congenital malformations of the nervous system; cleft palate and cleft lip; congenital malformations of the urinary tract). A control series of 109 children was selected using paired sampling. Thus, the next child to be born after a study child, and who survived the neonatal period, was chosen as a control. The number of controls was increased by also choosing the next neonatally surviving child born after a child with cerebral irritation or depression, diagnosed in the neonatal period, or after a stillborn infant or an infant who had died as a neonate. **Exclusion criteria:** NR
Interventions	**Drug class:** Benzodiazepines **Drug/s examined**: Oxazepam, phenobarbitone, levothyroxine, Nitrofuration, diazepam **Dosage:** Oxazepam 75 mg/day; Phenobarbitone 100 mg/day; Levothyroxine 0.15 mg/day; Nitrofurantoin 50 mg/day; Diazepam dose NR.
Outcomes	**Outcomes used:** Congenital malformation, major congenital malformations, cleft lip/palate **Outcomes not used:** Urinary system defect, nervous system defet (single study outcomes)
Study design	Case-control
Source of funding	Delegation for Social Research from the Swedish Ministry of Health and Welfare and the Swedish Medical Research Council, Grant numbers 07121, K88-25P-08465-01K, and Vilhelm and Martina Lundgrens Fund for Medical Research.
Limitations	
Notes	Malformations were: embryopathy and fetopathy, unspecified; unspecified congenital malformations of the nervous system; cleft palate and cleft lip; congenital malformations of the urinary tract

1.29.4 LAEGRID1992

Study ID	LAEGREID1992
Bibliographic reference	Laegreid, L., Hagberg, G., & Lundberg, A. (1992). Neurodevelopment in Late Infancy After Prenatal Exposure to Benzodiazepines-A Prospective Study*. Neuropediatrics, 23(02), 60-67 Laegreid, L., G. Hagberg, et al. (1992). The effect of benzodiazepines on the fetus and the newborn. Neuropediatrics 23: 18-23 Viggedal, G., B. S. Hagberg, et al. (1993). Mental development in late infancy after prenatal exposure to benzodiazepines. A prospective study. Journal of Child Psychology and Psychiatry and Allied Disciplines 34(3): 295-305
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records and interview **Country:** SE
Participants	**Trimester of exposure:** 1 **Duration of exposure:** NR **Total N:** 46

	N Exposed: 17 **N Unexposed:** 29 **Mean age (years):** NR **Diagnosis:** 87.5% anxiety disorder; 12.5% depression **Inclusion criteria:** From May 1984 to August 1986, the doctors at the general maternity outpatient units, the obstetricians at the two delivery departments and the psychiatrists in Gothenburg were asked to inform pregnant mothers using psychotropic drugs about the study and, if they were willing to participate, to refer them to the authors. Mothers who reported the regular use of psychotropic drugs without the use of street drugs (that is, cocaine, heroin, marijuana, amphetamines) or the abuse of alcohol were included. The control group was randomly selected from three maternity units in Gothenburg. These mothers were interviewed about their use of alcohol, cigarettes and prescribed and non-prescribed drugs in pregnancy. Urine samples were screened in early pregnancy for metabolites of BZD, marijuana, morphine, heroin, amphetamines, alcohol, phenobarbitone, meprobamate, codeine, propoxyphenc, salicylic acid and nicotine. Those mothers whose urine was found to be negative and who were not using psychoactive drugs or suffering from recorded psychiatric disease served as the reference group. **Exclusion criteria:** Three participants used BZD in combination with other psychotropic drugs and one delivered a boy with a Zellweger syndrome; these four were excluded from the study.
Interventions	**Drug class:** Benzdiazepines **Drug/s examined**: Any benzodiazepines **Dosage:** Oxazepam (11-60 mg daily), diazepam (5-30 mg daily) alone or in combination and lorazepam (5-15 mg daily).
Outcomes	**Outcomes used:** Major congenital malformaion, gestational age, birthweight, miscarriage, instrumentaldelivery, respiratory disorder **Outcomes not used:** N/A
Study design	Cohort
Source of funding	Grants from the Swedish Medical Research Council (No. K90-27P-8465-03A), the First of May Flower Annual Campaign for Children's Health, the Petter Silfverskiold Memorial Foundation, the Sunnerdahl Foundation and the Goteborgs Lakarsailskap Research Foundation.
Limitations	
Notes	Only major congneital malformations as an overall class used in meta-anlaysis (individual malformations could not be combined)

1.29.5 LEPPEE2010

Study ID	LEPPEE2010
Bibliographic reference	Leppee M, Culig J, Eric M, Sijanovic S. The effects of benzodiazepines in pregnancy. Acta Neurologica Belgica. 2010;110:163-67
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Medical records and self report questionnaire **Country:** Croatia
Participants	**Trimester of exposure:** Any **Duration of exposure:** NR **Total N:** 893

	N Exposed: 303 **N Unexposed:** 590 **Mean age (years):** NR **Diagnosis:** NR **Inclusion criteria:** The study was performed over a one-month period (May 1-31, 2004) at university departments of gynecology and obstetrics in four Zagreb hospitals. The study included all women who gave birth in that month **Exclusion criteria:** NR
Interventions	**Drug class:** Benzodiazepines **Drug/s examined:** Diazepam **Dosage:** NR
Outcomes	**Outcomes used:** Cardiac malformation **Outcomes not used:** Genitourinary defect
Study design	Cohort
Source of funding	No financial support.
Limitations	
Notes	

1.29.6 OBERLANDER2008

Study ID	OBERLANDER2008
Bibliographic reference	Oberlander TF, Warburton W, Misri S, Riggs W, Aghajanian J, Hertzman C. Major congenital malformations following prenatal exposure to serotonin reuptake inhibitors and benzodiazepines using population-based health data. Birth Defects Research Part B - Developmental and Reproductive Toxicology. 2008b;83:68-76
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** CA
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 108288 **N Exposed:** 968 **N Unexposed:** 107320 **Mean age (years):** 30 **Diagnosis:** NR **Inclusion criteria:** Cohorts were assembled from records of 203,520 registered live births (hospital and home births) in British Columbia occurring between April 1, 1997 and March 31, 2002. **Exclusion criteria:** To avoid any confounding effect from anticonvulsant exposure, and the inherent multiple maternal diagnoses and neonatal risks associated with these medications, records were removed where neonates had first trimester exposure to this class of medication.
Interventions	**Drug class: Benzodiazepines** **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**

Study design	Cohort
Source of funding	Funding from the BC Ministry of Children and Family development through the Human Early Learning Partnership. The authors also acknowledge the financial support of The Michael Smith Foundation for Health Research.
Limitations	
Notes	Also reports data for antidepressants (SSRIs)

1.29.7 ORNOY1998

Study ID	ORNOY1998
Bibliographic reference	Ornoy, A., J. Arnon, et al. (1998). Is benzodiazepine use during pregnancy really teratogenic? Reproductive Toxicology 12(5): 511-515.
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview and physician verification via letter **Country:** IL
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 1989 **N Exposed:** 599 **N Unexposed:** 1390 **Mean age (years):** 30 **Diagnosis:** NR **Inclusion criteria:** All women contacted the Israeli Teratogen Information Service (ITIS) regarding information on the possible risk to the developing embryo and fetus. The controls were all healthy women that contacted us because of the following nonteratogenic exposures: low dose x-rays to areas other than the abdomen and pelvis, topical dermatologic preparations not containing retinoids, analgesic drugs and oral contraceptives taken only for several weeks following the last menstrual period. **Exclusion criteria:** NR
Interventions	**Drug class: Benzodiazepines** **Drug/s examined:** Any **Dosage:** Alprazolam + carbamazepine 0.5 mg/week; Lorazepam + deralin 2 mg/d; Alprazolam only 0.5 mg/day – 1.5 mg/week; Clonazapam + carbamazepine 1 mg once; Diazepam + primonil 5 mg/d; Diazepam + penicillin 1 injection of 10 mg; Alprazolam, fluoxetine, + anafranil 1 mg/d; Lorazepam 2 mg/d; Clonazepam 2 mg occasionally; Lorazepam 0.5 mg/d alone.
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.29.8 PASTUSZAK1996

Study ID	PASTUSZAK1996
Bibliographic reference	Pastuszak, A., V. Milich, et al. (1996). Prospective assessment of pregnancy outcome following first trimester exposure to benzodiazepines. Canadian Journal of Clinical Pharmacology 3(4): 167-171.
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview and physician verification via letter **Country:** CA
Participants	**Trimester of exposure:** 1 **Duration of exposure:** 13 **Total N:** 274 **N Exposed:** 137 **N Unexposed:** 137 **Mean age (years):** NR **Diagnosis:** Exposed group: 41.6% anxiety disorders; 0.73% benzodiazepine abuse; 8.03% depression; 0.73% drug rehabilitation therapy; 16.06% insomnia; 0.73% obsessive compulsive disorder; 0.73% psychosis; 1.46% seizure. **Inclusion criteria:** Included all women prospectively counselled in the author's clinic (Motherisk Program) who were prospectively counselled about first trimester exposure to any BDZ between September 1986 and September 1991; each BDZ case was matched to a control temporally closest to the study case in a computerised database. **Exclusion criteria:** NR
Interventions	**Drug class: Benzodiazepines** **Drug/s examined:** Any **Dosage:** Benzodiazepine 0.07 – 202 mg/day.
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	NR
Limitations	
Notes	

1.29.9 WINKER2007

Study ID	WIKNER2007
Bibliographic reference	Wikner BN, Stiller CO, Bergman U, Asker C, Kallen B. Use of benzodiazepines and benzodiazepine receptor agonists during pregnancy: Neonatal outcome and congenital malformations. Pharmacoepidemiology and Drug Safety. 2007;16:1203-1210.
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Registries **Country:** SE
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 873879 **N Exposed:** 1979 **N Unexposed:** 871900

	Mean age (years): NR **Diagnosis:** NR **Inclusion criteria:** Information regarding the exposure to BZD and/or HBRA during pregnancy was obtained prospectively (that is, before the outcome of the pregnancy was known) for the period 1st July , 1995 to 31st December , 2004. All BZD and HBRA agents used in clinical practice in Sweden within this time frame were included in the analysis. **Exclusion criteria:** NR
Interventions	**Drug class: Benzodiazepines** **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	Grants from Knut and Alice Wallenberg Foundation and Evy and Gunnar Sandberg Foundation (BK), and the Karolinska Institute (CA). This study also received support from the EuroMaP concerted action in Biomed 2, contract no. BMH4CT97-2430(UB).
Limitations	
Notes	

1.30BENZODIAZEPINES – EXCLUDED STUDIES

Study	Reason for exclusion
Bonnot O, Vollset SE, Godet PF, D'Amato T, Robert E. Maternal exposure to lorazepam and anal atresia in newborns: Results from a hypothesis-generating study of benzodiazepines and malformations. Journal of Clinical Psychopharmacology. 2001;21:456-58	Data not available to calculate actual event rates and unadjusted ORs. Unexposed comparison group unclear.
Correa-Villasenor A, Ferencz C, Neill CA, Wilson PD, Boughman JA. Ebstein's malformation of the tricuspid valve: genetic and environmental factors. The Baltimore-Washington Infant Study Group. Teratology. 1994;50: 137-47	Data can not be extracted

Czeizel AE, Eros E, Rockenbauer M, Sorensen HT, Olsen J. Short-term oral diazepam treatment during pregnancy: a population-based teratological case-control study. Clinical Drug Investigation. 2003;23:451-62	Data not extracted for exposure during first trimester only as N not available. DATA REQUEST Raw event rates for congenital abnormalities split by exposed and unexposed
Czeizel AE, Rockenbauer M, Sorensen HT, Olsen J. A population-based case-control study of oral chlordiazepoxide use during pregnancy and risk of congenital abnormalities. Neurotoxicology & Teratology. 2004;26:593-8	Data not extracted for exposure during first trimester only as N not available. DATA REQUEST Raw event rates for congenital abnormalities split by exposed and unexposed
Czeizel AE, Szegal BA, Joffe JM, Racz J. The effect of diazepam and promethazine treatment during pregnancy on the somatic development of human offspring. Neurotoxicology and Teratology. 1999;21:157-67	Comparison group combines data from 'positive and negative control groups' in the study. awaiting author response DATA REQUEST Raw event rates for congenital abnormalities split by exposed and unexposed
Diav-Citrin O, Okotore B, Lucarelli K, Koren G. Pregnancy outcome following first-trimester exposure to zopiclone: a prospective controlled cohort study. American Journal of Perinatology. 1999;16:157-60	Data for 'Zopiclone', not strictly a benzodiazepine, buit a related drug. No other studies report data for zopicline therefore could not be included in mta-analysis
Eros E, Czeizel AE, Rockenbauer M, Sorensen HT, Olsen J. A population-based case-control teratologic study of nitrazepam, medazepam, tofisopam, alprazolum and clonazepam treatment during pregnancy. European Journal of Obstetrics Gynecology and Reproductive Biology. 2002;101:147-54.	Same register as Czeizel 1988; 2003; 2005. DATA REQUEST Raw event rates for congenital abnormalities split by exposed and unexposed
Kjaer D, Horvath-Puho E, Christensen J, Vestergaard M, Czeizel AE, Sorensen HT, et al. Use of phenytoin, phenobarbital, or diazepam during pregnancy and risk of congenital abnormalities: a case-time-control study. Pharmacoepidemiology and Drug Safety. 2007;16:181-88.	Only ORs reported unable to calculate raw event rates, therefore could not be conbined in meta-analysis
Wan LH, Lin CC, Chen YH, Lin HC. Increased risk of adverse pregnancy outcomes in women receiving zolpidem during pregnancy. Clinical Pharmacology and Therapeutics. 2010;88: 369-374	Single study outcomes

1.31 LITHIUM – INCLUDED STUDIES

1.31.1 BODEN2012A

See 1.25.2.

1.31.2 CORREA-VILLASENOR1994

Study ID	CORREA-VILLASENOR1994
Bibliographic reference	Correa-Villasenor A, Ferencz C, Neill CA, Wilson PD, Boughman JA. Ebstein's malformation of the tricuspid valve: genetic and environmental factors. The Baltimore-Washington Infant Study Group. Teratology. 1994;50:137-47
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Face-to-face interview **Country:** US
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 6947 **N Exposed:** 92 **N Unexposed:** 6855 **Mean age (years):** 13.51% <20; 15.47% 20-29; 31.68% = >30 **Diagnosis:** NR **Inclusion criteria:** The study population arose from the resident live births of a defined area including the State of Maryland, the District of Columbia, and six counties of northern Virginia. Infants with cardiovascular malformations (CVM) ascertained from multiple sources and confirmed before 1 year of age by echocardiography, cardiac catheterization, surgery, or autopsy were included as CVM cases. The case group in this report is comprised of liveborn infants with Ebstein's anomaly of the tricuspid valve. Control infants without CVM were selected from area hospitals by a computer algorithm to achieve a representative sample of the regional livebirth cohort. As an additional comparison group, this report also evaluates data on infants who had CVM other than Ebstein's anomaly. **Exclusion criteria:** NR
Interventions	**Drug class: Lithium** **Drug/s examined:** Any **Dosage:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Case-control
Source of funding	Grant R37- HL25629 from the National Heart, Lung, and Blood Institute, NIH, and grant R29-ES06218 from the National Institute of Environmental Health Sciences, NIH.
Limitations	
Notes	

1.31.3 CZEIZEL1990

Study ID	CZEIZEL1990
Bibliographic reference	Czeizel A, Racz J. Evaluation of drug intake during pregnancy in the Hungarian Case-Control Surveillance of Congenital Anomalies. Teratology. 1990;42:505-12
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Questionnaire **Country:** HU
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 32244 **N Exposed:** 11 **N Unexposed:** 32233 **Mean age (years):** 25 **Diagnosis:** Not reported **Inclusion criteria:** Selection of the record cards of index patients with major isolated CAs and unidentified multiple CAs from the data base of the HCMR for t,he study group. Index patients with Down syndrome are also selected but these cases are evaluated separately as a positive control group. Three negative controls, that is, newborns without CAs, are matched to every index patient according to sex, birth week, and district of parents' residence from the national birth registry of the Central Statistical Office **Exclusion criteria:** Index patients with mild CAs such as congenital dislocation of hip, congenital inguinal hernia, hemangiomas, etc.; minor variants; and CA syndromes of known origin were excluded.
Interventions	**Drug class:** Lithium **Drug/s examined:** Lithium **Dosage:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Case-control
Source of funding	N/R
Limitations	
Notes	

1.31.4 JACOBSON1992

Study ID	JACOBSON1992
Bibliographic reference	Jacobson SJ, Jones K, Johnson K, Ceolin L, Kaur P, Sahn D, et al. Prospective multicentre study of pregnancy outcome after lithium exposure during first trimester. Lancet. 1992;339:530-33
Methods	**Prospective/Retrospective:** Prospective **Data collection:** Telephone interview **Country:** US
Participants	**Trimester of exposure:** 1 **Duration of exposure:** Not reported **Total N:** 286

	N Exposed: 138 **N Unexposed:** 148 **Mean age (years):** 30 **Diagnosis:** NR **Inclusion criteria:** Enrolled 148 women who called one of four teratogen information services to obtain information about the potential risks of therapeutic drugs during pregnancy: these centres were Motherisk (Toronto), the California Teratogen Information Service (CTIS) (San Diego), the Philadelphia Pregnancy Healthline, and Foetal Risk Assessment from Maternal Exposure (FRAME) (London, Ontario). All pregnant women who called during 1985-1989 and who reported lithium ingestion during part or all of their first trimester were prospectively enrolled. Lithium exposures as early as 3 weeks' gestation were included. Controls were women who were seen at the Motherisk clinic for counselling about drugs that are not known or suspected to be teratogenic. Each study patient was matched with a woman of similar age (to within 2 years). **Exclusion criteria:** NR
Interventions	**Drug class:** Lithium **Drug/s examined:** Lithium **Dosage:** Mean daily dose = 927 (340) mg
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.31.5 KALLEN1983

Study ID	KALLEN1983
Bibliographic reference	Kallen B, Tandberg A. Lithium and pregnancy. A cohort study on manic-depressive women. Acta Psychiatrica Scandinavica. 1983;68:134-39
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** SE
Participants	**Trimester of exposure:** Not reported **Duration of exposure:** Not reported **Total N:** 121 **N Exposed:** 41 **N Unexposed:** 80 **Mean age (years):** Unclear **Diagnosis:** **Inclusion criteria:** Women from central registries and information from hospital charts. Infants born in 1973-1979 of women who had, during tht period, been treated as inpatients for manic-depressive disease **Exclusion criteria:** NR
Interventions	**Drug class:** Lithium **Drug/s examined:** Lithium

	Dosage: NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.31.6 REIS2008

See above

1.32 LITHIUM – EXCLUDED STUDIES

Study	Reason for exclusion
Czeizel A, Rac J. Evaluation of drug intake during pregnancy in the Hungarian case-control surveillance of congenital anomalies. Teratology 1990;42:505–512	Only 6 infnats exposed to lithium
van der Lugt NM, van de Maat JS. et al. Fetal, neonatal and developmental outcomes of lithium-exposed pregnancies. Early Human Development. 2012;88:375-378	No unexposed control group
Zalzstein E, Koren G et al. A case-control study on the association between first trimester exposure to lithium and Ebstein's anomaly. American Journal of Cardiology. 1990; 65:817-818	No exposure to lithiumnoted
Weinstein MR and Goldfield MD. Cardiovascular malformations with lithium use during pregnancy. The American Journal of Psychiatry. 1975;132: 529-531	No contorl group

1.33 STIMULANTS – INCLUDED STUDIES

1.33.1 POTTEGARD2014

Study ID	POTTEGARD2014
Bibliographic reference	Pottegard A, Hallas J, Andersen JT, Lokkegaard ECL, Dideriksen D, Aagaard L. First-trimester Exposure to Methylphenidate: A population-Based Cohort Study. Journal of Clinical Psychiatry. 2014:75;e88-e93
Methods	**Prospective/Retrospective:** Retrospective **Data collection:** Registries **Country:** DE
Participants	**Trimester of exposure:** 2 **Duration of exposure:** Not reported **Total N:** 2442 **N Exposed:** 222 **N Unexposed:** 2220 **Mean age (years):** NR (matched for age) **Diagnosis:** **Inclusion criteria:** Pregnancies identified using the Medical Birth Registry. Only included pregnancies resulting in live births. First trimester exposure

	(15th day to the 84th day). To be included mother had to have first trimester exposure to methylphenidate, required to redeem 1 or more prescriptions within a time window defined as 14 days before the beginning of the first trimester up to the end of the first trimester **Exclusion criteria:** Spontaneous and elective abortions not included. Excluded multiple gestation pregnancies, pregnancies in which the mother migrated to or from Denmark within 5 years prior to the initiation of the pregnancy, and pregnancies in which the child migrated from Denmark within 6 months after being born. Excluded pregnancies during which the mother had used certain drugs tht are rarely used during pregnancy but known to be teratogenic
Interventions	**Drug class:** Stimulants **Drug/s examined:** Methylphenidate **Dosage:** NR
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Cohort
Source of funding	N/R
Limitations	
Notes	

1.34STIMULANTS – EXCLUDED STUDIES

Study	Reason for exclusion
Wajnberg R, Diav-Citrin O, Shechtman S, Ornoy A. Pregnancy outcome after in-utero exposure to methlphenidate: a prospective comparative sohort study. Reproductive Toxicology. 2011;13:255-268	No access (and no unexposed control group)
Briggs GG, Freeman RK, Yaffe SJ. Drugs in Pregnancy and Lactation, 9th edn. Lippincott Williams and Wilkins, Philadelphia. 2011;942-943	No access (and no unexposed control group)
Heinonen OP, Slone D, Shapiro S. Birth defects and Drugs in Pregnancy. Pubishig Science Group, Littleton, MA. 1977;346-347	No access (and no unexposed control group)
Metylfenidat. Lakemedel och fosterpaverkan. http://www.janusinfose. (last accessed on 12 September 2012)	No access (and no unexposed control group)

1.35 PHYSICAL INTERVENTIONS: PREVENTION (NO RISK FACTORS IDENTIFIED)

1.35.1 NORMAN2010

Study ID	NORMAN2010
Bibliographic reference	Norman E, Sherburn M, Osborne RH, Galea MP. An exercise and education program 16 improves well-being of new mothers: a randomized controlled trial. Physical 17 therapy. 2010;90:348-55.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** Hospital and home **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS: experimental group = 8.00 (6.16); control group = 6.75 (5.44) **N (number randomised):** 161 **Mean age (years):** 30 **Risk factor/s:** Not applicable **Inclusion criteria:** i) Primiparous and multiparous women ready for discharge; ii) spoke and read English independently **Exclusion criteria:** i) A diagnosis of a psychiatric disorder medicated and managed by a general practitioner/ psychiatrist; ii) women who needed hospitalization
Interventions	**Experimental intervention** **Name:** Mother and Baby (M&B) group (Physical activity + psychoeducation) **Description:** The M&B Program was conducted once per week for 8 weeks at The Angliss Hospital. Each week, women undertook 1 hour of group exercise with their babies, facilitated by a physical therapist, which involved cardiovascular and strength components. Each of the 8 exercise sessions was adapted for each woman depending on the type of delivery and her recovery. Participants also had a 30-minute education session delivered by health care professionals. In addition, the M&B group received the same written educational material as the EO group. In the last week of the program, all the speakers and the women and their babies gathered together for afternoon tea. Both groups received a booklet containing diagrams of all the exercises provided over course of the program, as well as a list of local gyms and community resources to assist them in continuing their exercise at home. **Format:** Group and Individual (booklet) **Group size:** NR **Sessions:** 8 **Frequency (number of doses per week):** 1 **Duration (weeks): 8** **Provider:** Health care professionals (physical therapists, dieticians, speech pathologists, health psychologists, midwives) **Control intervention** **Name:** Education only (EO) group (psychoeducation) **Description:** The EO group received written educational material mailed to them every week over 8 weeks. Education topics covered baby massage,

	nutrition for mothers, introducing solids, adjusting to a new lifestyle, communicating with the baby, sun care for the baby, and play development. Contact details of health care personnel also were included in this written information. **Format:** Individual (booklet) **Group size:** N/A **Sessions: 8** **Frequency (number of doses per week): 1** **Duration (weeks): 8** **Provider:** N/A
Outcomes	**Outcomes used:** Depression mean scores (EPDS) **Outcomes not used:** Positive affective balance scales mean scores; Physical activity mean scores; drop out
Study design	Randomised controlled trial (RCT)
Source of funding	The Angliss Hospital and the Rehabilitation Sciences Research Centre, University of Melbourne.
Limitations	1. High risk of attrition bias due to greater number of participants not comencing intervention randomised to in the intervetion group 18/80 compared with the control 8/81 2. Unclear risk of selection bias as EPDS at baseline higher in the experimental (8.00 [6.16]) than control (6.75 [5.44]) group 3. High risk of performance bias as it was not possible to blind participants or personnel
Notes	Protocol registered NCT00361478.

1.35.2ROBLEDO-COLONIA2012

Study ID	ROBLEDO-COLONIA2012
Bibliographic reference	Robledo-Colonia AF, Sandoval-Restrepo N, Mosquera-Valderrama YF, Escobar-27 Hurtado C, Ramirez-Velez R. Aerobic exercise training during pregnancy reduces 28 depressive symptoms in nulliparous women: a randomised trial. Journal of 29 Physiotherapy. 2012;58:9-15.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Yes **Setting:** Hospital **Country:** Colombia
Participants	**Timing:** Antenatal **Baseline symptoms:** Baseline CES-D = 16.5 (7.5) **N (number randomised):** 80 **Mean age (years):** 21 **Risk factor/s:** N/A **Inclusion criteria:** i) Aged between 16 and 30 years; ii) Between 16 and 20 weeks gestation; iii) with a live foetus at the routine ultrasound scan **Exclusion criteria:** i) Had participated in a structured exercise program in the past six months; ii) Had a history of high blood pressure, chronic medical illness; iii) persistent bleeding after week 12 of gestation; iv) poorly controlled thyroid disease, placenta praevia, incompetent cervix, polyhydramnios, oligohydramnios, miscarriage in the last 12 months, or diseases that could interfere with participation
Interventions	**Experimental intervention** **Name:** Supervised exercise program **Description:** Supervised group exercise sessions comprising three to five women. Sessions consisted of walking (10 mins), aerobic exercise (30 mins), stretching (10 mins), and relaxation (10 mins). Aerobic activities were prescribed at moderate to vigorous intensity, aiming for 55-75% of maximal heart rate and adjusted according to ratings on the Borg scale. Adherence to the excercise program was encouraged by the physiotherapist who supervised the excercise sessions. In order to maximise adherence to the training program, all sessions were: supervised by a physiotherapist and a physician, conducted in groups of three to five women, accompanied by music, and performed in a spacious, air-conditioned room. **Format:** Group **Group size:** 3-5 **Sessions:** 39 **Frequency (number of doses per week):** 3 **Duration (weeks):** 13 **Provider:** Physiotherapist **Control intervention** **Name:** Treatment as usual **Description:** Received no exercise intervention, did not attend the exercise classes, and did not take part in a home exercise program. Both groups continued with their normal prenatal care (1 session per week for 3 months) and physical activity **Format:** Individual **Group size:** N/A

	Sessions: Not reported **Frequency (number of doses per week):** N/A **Duration (weeks):** 13 **Provider:** NR
Outcomes	**Outcomes used:** CES-D, drop-out **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	COLCIENCIAS (Grant No 1106-459921540)
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Possible selective reporting bias; protocol states it is a 4 armed trial. Only 2 arms of the trial are reported in the paper
Notes	Protocol registered: NCT00872365

1.35.3 SONGOYGARD2011

Study ID	SONGOYGARD2011
Bibliographic reference	Songoygard KM, Stafne SN, Evensen KA, Salvesen KA, Vik T, Morkved, S. Does 19 exercise during pregnancy prevent postnatal depression? A randomized controlled 20 trial. Acta Obstetricia et Gynecologica Scandinavica. 2012;91:62-7.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** and home **Country:** Norway
Participants	**Timing:** Antenatal **Baseline symptoms:** NR **N (number randomised):** 855 **Mean age (years):** 31 **Risk factor/s:** N/A **Inclusion criteria:** i) Pregnant women living in the cities of Trondheim and Stavanger, Norway, attending a routine ultrasound examination at 18weeks of pregnancy; ii) 18years or older, with a singleton live fetus **Exclusion criteria:** i) Pregnancy complications; ii) High risk for preterm delivery or diseases that could interfere with participation
Interventions	**Experimental intervention** **Name:** Exercise group **Description:** The intervention group followed a specially designed exercise program, including aerobic activity, specific exercises for stabilization of the lower back and pelvis, specific exercises for the pelvic floor muscles and general exercises, including balance exercises. Also received written information containing advice on diet, pelvic floor muscle exercises and pregnancy-related pelvic girdle pain. **Format:** Group **Group size:** NR **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Physiotherapists **Control intervention** **Name:** Treatment as usual **Description:** The women in the control group received the customary information provided by their midwife or general practitioner. Also received written information containing advice on diet, pelvic floor muscle exercises and pregnancy-related pelvic girdle pain. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 12 **Provider:** midwife or general practitioner
Outcomes	**Outcomes used:** Depression symptomology (EPDS >10; >13) **Outcomes not used: NR**

Study design	Randomised controlled trial (RCT)
Source of funding	No specific funding.
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel
Notes	Protocol registered: NCT 00476567. Pulblication automatically indexed to the protocol study, although the main outcomes in 2 additional publications are gestational diabetes and lumbopelvic pain.

1.36 PHYSICAL INTERVENTIONS: PREVENTION (NO RISK FACTORS) – EXCLUDED STUDIES

Study	Reason for exclusion
Bastani F, Hidarnia A, Montgomery KS, Aguilar-Vafaei ME, Kazemnejad A. Does relaxation education in anxious primigravid Iranian women influence adverse pregnancy outcomes? A randomized controlled trial. Journal of Perinatal and Neonatal Nursing. 2006;20:138-146	No mental health outcomes
Bazrafshan MR, Ghorbani Z. The Effect of Slow Stroke Back Massages on Anxiety among Primigravid Women [Farsi]. Hayat. 2010;16): 34-40	Non-English
Ji ES, Han HR. The effects of Qi exercise on maternal/fetal interaction and maternal well-being during pregnancy. JOGNN: Journal of Obstetric, Gynecologic, & Neonatal Nursing. 2010;39: 310-318	Not an RCT
Ko YL, Yang CL, Chiang LC. Effects of postpartum exercise program on fatigue and depression during "doing-the-month" period. Journal of Nursing Research. 2010;16:177-186	Not an RCT
Kordi M, Nasiri S, Gharavi MM, Ebrahimzadeh S. Evaluating the effect of progressive muscle relaxation training with guided imagery on the severity of depressive symptoms in postpartum period. Iranian Journal of Obstetrics, Gynecology and Infertility. 2012;15:17-24	Non-English
Da Silva JBG.Acupuncture for mild to moderate emotional complaints in pregnancy – A prospective, quasi-randomised, controlled study. Acupuncture in Medicine. 2007;25: 65-71	Not an RCT
Urech C, Fink NS, Hoesli I, Wilhelm FH, Bitzer J, Alder J. Effects of relaxation on psychobiological wellbeing during pregnancy: A randomized controlled trial. Psychoneuroendocrinology. 2010;35: 1348-1355.	Data cannot be extracted

1.37PHYSICAL INTERVENTIONS: PREVENTION (IDENTIFIED RISK FACTORS) – INCLUDED STUDIES

1.37.1HADDAD-RODRIGUES2013

Study ID	HADDAD-RODRIGUES2013
Bibliographic reference	Haddad-Rodrigues M, Nakano AMS, Stefanello J, Silveira RCCP. Acupuncture for Anxiety in Lactating Mothers with Preterm Infants: A Randomized Controlled Trial. Evidence-Based Complementary and Alternative Medicine. 2013;2013:169184
Methods	**Blinding of participants:** Yes **Blinding of personnel:** No **Blinding of outcome assessment:** Yes **Setting:** Tertiary school hospital **Country:** Brazil
Participants	**Timing:** Postnatal **Baseline symptoms:** STAI- Trait, 44.41 (10.05) **N (number randomised):** 29 **Mean age (years):** 27 **Risk factor/s:** Preterm infants, very low birthweight (<1500g) **Inclusion criteria:** i) All women who gave birth to very low birth weight infants (<1500 g) ; ii) women's hospital discharge date within 7 days after delivery, iii) reading and writing literacy; iv) infant who was not breastfeeding, and; v) residence within 50 Km range from the hospital. **Exclusion criteria:** i) use of galactogogues; ii) use of contraceptive pills or any other drug contraindicated during breastfeeding; iii) seropositivity for HIV or HTLV-1 and HTLV-2; iv) presenting with any health condition which contraindicated breastfeeding such as alcohol or drug (a) shenmen; (b) muscle relaxation; (c) tension; (d) anxiety 1 and 2; v) abuse and psychiatric disorders; vi) former acupuncture patients.
Interventions	**Experimental intervention** **Name:** Acupuncture **Description:** A total of 5 ear acupoints were selected based on their indication for anxiety, Shenmen, tension, muscle relaxation, anxiety 1 and 2, and were located according to the Chinese Ear Acupuncture chart. All 5 points were used in the sessions and retained until the next appointment. Initially the needles were inserted at subject's dominant side, applied in one ear at a time, alternating sides between sessions. Before application, the ear was sanitized with 70% alcohol ad benzoin tincture was applied ar acupuncture points to improve needle fixation. Real acupuncture was applied using sterile disposable stainless steel needles (1.0mm x 1.5 mm) **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 12 **Provider:** Licensed nurse acupuncturist **Control intervention** **Name:** Placebo **Description:** Placebo acupuncture was applied using the same needles customised to not perforate skin. A toothpick was used to create the ensation of

	needle perforation. After needle insertion a 1cm2 beige micropore tape was placed on top of each needle for fixation **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 12 **Provider:** Licensed nurse acupuncturist
Outcomes	**Outcomes used:** STAI, cortisol levels **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	
Limitations	
Notes	Have taken figures from the text as assumed error in the table (figures are reported the wrong way round for AG and PG)

1.38 PHYSICAL INTERVENTIONS: PREVENTION (IDENTIFIED RISK FACTORS) – EXCLUDED STUDIES

Study	Reason for exclusion
Miles R, Cowan F, Glover V, Stevenson J, Modi N. A controlled trial of skin-to-skin contact in extremely preterm infants. Early Human Development. 2006;82: 447-455	Not an RCT

1.39 PHYSICAL INTERVENTIONS: TREATMENT – INCLUDED STUDIES

1.39.1 ARMSTRONG2004

Study ID	ARMSTRONG2004
Bibliographic reference	Armstrong K, Edwards H. The effectiveness of a pram-walking exercise programme 37 in reducing depressive symptomatology for postnatal women. International Journal 38 of Nursing Practice. 2004;10:177-94.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Country:** Australia
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS mean (SD): pram-walking group (n=9) 17.25 (4.00); support group (n=10) 17.17 (4.45) . 100% depressive symptomology by EPDS >=12 **N (number randomised):** 24 **Mean age (years):** NR **Risk factor/s:** N/A **Inclusion criteria:** i) Living in the Gold Coast region of Queensland; ii) have a child aged 6 weeks to 12 months; iii) EPDS score = >12 **Exclusion criteria:** i) Had a medical condition that would prevent regular aerobic exercise
Interventions	**Experimental intervention** **Name:** Pram walking exercise programme **Description:** Pram-walking towards target heart-rate; muscle stretches **Format:** Group **Group size:** NR **Sessions:** 24 **Frequency (number of doses per week):** 2 **Duration (weeks):** 12 **Provider:** Facilitators (nurse/social worker) **Control intervention** **Name:** Social support group **Description:** Unstructured discussion for social and emotional but not practical support. Baby/child welcome. **Format:** Group **Group size:** NR **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Nurse/social worker
Outcomes	**Outcomes used:** Drop-out; Depression mean scores (EPDS); Social support (SSI) **Outcomes not used:** Data not extracted for 6-week follow-up as mid-treatment. Data not extracted for physical fitness outcomes. Paper reports available case and not possible to compute ITT (WCS).
Study design	Randomised controlled trial (RCT)

Source of funding	NR
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of attrition bias- Paper reports available case and not possible to compute ITT (WCS).
Notes	Not protocol registered

1.39.2 DALEY2008

Study ID	DALEY2008
Bibliographic reference	Daley A, Winter H, Grimmett C, McGuinness M, McManus R, MacArthur C. 7 Feasibility of an exercise intervention for women with postnatal depression: A pilot 8 randomised controlled trial." British Journal of General Practice. 2008;58:178-183
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** GP and Home **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** >12 on the EPDS **N (number randomised):** 38 **Mean age (years):** NR **Risk factor/s:** N/A **Inclusion criteria:** i) Women aged 16 years or more; ii) experiencing depression; iii) and whose youngest child was less than 12 months; iv) Participants could continue with prescribed medications and any counselling/behavioural treatments, but had to speak English because of lack of interpretation services; v) score >12 on the Edinburgh Postnatal Depression Scale **Exclusion criteria:** i) Women with severe postnatal depression who required inpatient psychiatric treatment; ii) had psychotic symptoms, or were known to be pregnant
Interventions	**Experimental intervention** **Name:** Exercise **Description:** Participants in the intervention group were offered two one-to-one exercise consultations over the 12-week intervention period. The intervention aimed to equip individuals with the skills, knowledge, and confidence needed to participate in regular exercise, and was delivered in participants' homes by a trained researcher. Consultations lasted about 1 hour.The first consultation focused on uptake of exercise and enhancing motivation, self-efficacy for exercise, overcoming barriers, and developing appropriate activity goals. Participants were also given a pedometer. A short 'walk and talk' pram-pushing session was incorporated within the first consultation so that practical issues, such as perceived exertion monitoring and exercise safety, could be explored with participants. Four weeks later, a second consultation focused on the prevention of relapse back to sedentary behaviour and/or improving maintenance of an active lifestyle. Follow-up support phone calls lasting about 10 minutes were given during weeks 3 and 9, where any persistent barriers or issues preventing behavioural change were

	discussed. The behavioural goal was for women to work towards accumulating participation in moderateintensity activities for at least 30 minutes per day, five days of the week. Walking in the form of 'pram pushing' was advocated and, when appropriate, opportunities for women to exercise without their baby were discussed. **Format:** Individual **Group size:** N/A **Sessions:** 2 consultations (plus follow-up phone calls) **Frequency (number of doses per week):** Unclear **Duration (weeks):** 12 **Provider:** trained researcher **Control intervention** **Name:** Treatment as usual **Description:** Members of the usual care group were asked not to change their current exercise patterns but were offered an exercise consultation at the end of their involvement in the study. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 12 **Provider:** NR
Outcomes	**Outcomes used:** EPDS **Outcomes not used:** Intensity of exercise outcomes
Study design	Randomised controlled trial (RCT)
Source of funding	Midlands Research Practice Consortium (MidReC).
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Unclear risk of attrition bias
Notes	Data requested and provided by email contact from the author

1.39.3 DALEY2014

Study ID	DALEY2014
Bibliographic reference	Daley AJ, Blamey RV, Jolly K, Roalfe AK, Turner KM, Coleman S et al. A pragmatic 10 randomised controlled trial to evaluate the effectiveness of exercise as a treatment 11 for postnatal depression: the PAM-PeRS trial.(in press).
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** All ICD-10 criteria for major depression. EPDS 13.4 (5.5) **N (number randomised):** 94 **Mean age (years):** 30 **Risk factor/s:** N/A **Inclusion criteria:** i) within six months of giving birth; ii) aged 18 years or over; iii) had an ICD-10 diagnosis of a major depressive episode, following

	initial screening using the Edinburgh Postnatal Depression Scale and a clinical diagnostic interview; iv) Women with a diagnosis of mixed anxiety and depression were also eligible; v) women needed to be currently inactive (defined as not meeting the current public health guidelines for physical activity of <150 minutes of moderate intensity physical activity per week in the previous 7 days); vi) proficient in English at a level to complete the initial screening **Exclusion criteria:** i) if women were pregnant again; ii) experiencing psychotic symptoms or dependent on illicit drugs or alcohol or otherwise unsuitable; iii) Women whose babies had died or who were not living with the baby
Interventions	**Experimental intervention** **Name:** Physical activity group **Description:** Offered two face to face consultations and two telephone support calls with a physical activity facilitator over six months to support participants to engage in regular exercise. Leaflets to further prompt exercise were mailed throughout the intervention.The initial goal (weeks 1-12) was for participants to progress towards accumulating 30 minutes of moderate intensity exercise on three days per week. During weeks 13-24 participants were encouraged to work towards accumulating 30 minutes of moderate intensity exercise on 3-5 days per week. The exercise intervention lasted six months. Similar to our pilot trial15 the intervention involved two face to face personalised exercise consultations (during months 1 and 2) and telephone calls (during months 3 and 4). In addition, participants were mailed information leaflets throughout the intervention **Format:** Individual **Group size:** N/A **Sessions:** two face to face consultations and two telephone support calls **Frequency (number of doses per week):** Variable **Duration (weeks):** 26 **Provider:** Physical activity facilitator **Control intervention** **Name:** Treatment as usual **Description:** There was no interference with usual care. The GP and participants could decide on any necessary treatment. The usual care group were sent the study "Looking after yourself" leaflet at baseline and exercise was not further encouraged beyond receipt of this single leaflet. **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 26 **Provider:** NR
Outcomes	**Outcomes used:** EPDS mean scre at 6 months and 1 year postnatal **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. Unclear risk of attrition bias
Notes	

1.39.4 CHUNG2012

Study ID	CHUNG2012
Bibliographic reference	Chung KF, Yeung WF, Zhang ZJ, Yung KP, Man SC, Lee CP et al. Randomized non-19 invasive sham-controlled pilot trial of electroacupuncture for postpartum 20 depression. Journal of Affective Disorders. 2012;142:115-21.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** Self-report **Setting:** **Country:** China
Participants	**Timing:** Postnatal **Baseline symptoms:** DSM-IV MDD, HDRS score 12-19 **N (number randomised):** 20 **Mean age (years):** 35 **Risk factor/s:** N/A **Inclusion criteria**: (1)ethnic Chinese and permanent residents in Hong Kong; (2) aged 18 years or above; (3) within six months of giving birth; (4) EPDS score >12; (5)diagnosis of major depressive disorder based on the DSM-IV criteria, asassessed by clinician; (6)17-item HDRS score of 12 to 19 at screening and baseline assessment; and (7) sufficient understanding of trial protocol and willingness to give informed consent and comply with the protocol **Exclusion criteria:** (1) had previous diagnosis of schizophrenia, other psychotic disorders, bipolar disorder, or alcohol or substance use disorder; (2) had a significant risk of suicide or Infanticide according to the clinician; (3) had any serious physical illness; (4) had valvular heart defects or bleeding disorders or were taking anticoagulant drugs; (5) had infection or abscess close the site of selected acupoints; (6)received acupuncture during the previous 12 months prior to baseline; (7) were taking herbal remedies or psychotropic drugs that were intended for depression within the last two weeks prior to baseline or during the study; or (8) were receiving counselling or psychological therapies at baseline or during the study.
Interventions	**Experimental intervention** **Name:** Electroacupuncture **Description:** Subjects assigned to electroacupuncture were needled at cranial and body acupoints. Cranial acupoints include six pairs: Baihui (DU20), Yintang(EX-HN3), left Sishencong (EX-HN1)and Toulinqi (GB15), right Sishencong (EX-HN1) and Toulinqi (GB15), bilateral Shuaigu (GB8), bilateral Taiyang (EX-HN5), and bilateral Touwei (ST8). Body acupoints include bilateral Sanyinjiao (SP6), bilateral Taichong (LR3), Shenmen (HE7) and Neiguan(PC6). According to a recent systematic review(Zhang etal.,2010) and expert consensus, the acupoints are empirical for treating depression in term of traditoanal Chinese medicine theory. Skin around acupoints was sterilized by 75% alcohol. Sterilized disposable needle (0.3mm in diameter and 25–40mm in length) were inserted at a depth of 10–30mm obliquely orperpendicuarly into acupoints. The needles were twisted and thrust forward and backward to achieve''deqi''(an irradiating feeling considered to be indicative of effective needling). Anelectric-stimulator (Hwato, SDZ-II, China) was connected to the needles and delivered a 6 volt, biphasic triangular, brief-pulse stimulus in 2-Hz frequency to the subjects. The needles were left for 30 min and then removed.

	Format: Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** 2 **Duration (weeks):** 4 **Provider:** Acupuncturist **Control intervention** **Name:** Non-invasive sham acupuncture **Description:** Subjects were treated at the same acupoints using Streitber- ger's placebo needles. The blunt needle was not fixed inside the copper handle. When its tip touched the skin, a pricking sensation was felt by the subject, thereby simulating the puncturing of the skin. The needle moved inside the handle and appeared to be shortened. A previous studiy showed that the credibility of placebo needles was high, particularly in acupuncture-naı¨ve subjects. Similar to the technique used in the electrocaupucnture group, the needles were held by surgical tape or hair pins and connected to the same electric stimulator using the same stimulation modality. Since the subjects were lying in bed and all acupoints were beyond their visual field, they were unlikely to have noticed the needling procedure. The acupuncturist, setting, treatment frequency, and duration of the treatment course were the same as in the electroacupuncture group. **Format:** Individual **Group size:** N/A **Sessions:** 8 **Frequency (number of doses per week):** 2 **Duration (weeks): 4** **Provider:** Acupuncturist
Outcomes	**Outcomes used:** Mean depression scores (EPDS), anxiety (HADS); non-response to treatment (CGI) at 4 week follow-up **Outcomes not used:** Depression (HRSD) Sheehan Disability Scale, Credibility of Treatment Rating Scale, Adverse events, leaving the study early
Study design	Randomised controlled trial (RCT)
Source of funding	Funding source of the study has no archiving requirements attached to the funding
Limitations	1. High risk of performance bias as it was not possible to blind participants or personnel 2. High risk of attrition bias (large and unequal drop out)
Notes	protocol registered NCT01178008

1.39.5 FIELD2013B

Study ID	FIELD2013B
Bibliographic reference	Field T, Diego M, Delgado J, Medina L. Tai chi/yoga reduces prenatal depression, anxiety and sleep disturbances. Complementry Therapy Clinical Practice. 2013b;19:6-10.
Methods	**Blinding of participants:** No **Blinding of personnel:** No **Blinding of outcome assessment:** Self-report **Setting:** Prenatal clinic **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** CES-D tai chi/yoga = 32.4 (10.2), control = 26.7 (11.2) **N (number randomised):** 92 **Mean age (years):** 27 **Risk factor/s:** N/A **Inclusion criteria:** i) meeting diagnostic criteria for depression on the Structured Clinical Interview for Depression (SCID); ii) being pregnant with one child; iii) having an uncomplicated pregnancy with no medical illness; iv) being younger than 40 years-old; v) not using drugs (that is, prescribed or illicit). [Previous samples recruited from these clinics had a very low incidence (3–5%) of treatment for prenatal depression (that is, psychotherapy or antidepressants), so these were not exclusion criteria] **Exclusion criteria:** NR
Interventions	**Experimental intervention** **Name:** Physical activity (Tai-chi/yoga) **Description:** Women in the tai chi/yoga group participated in a 20 min session per week for a period of 12 weeks. A trained yoga instructor led group participants through a routine specifically designed for women in their second and third trimester of pregnancy **Format:** Group **Group size:** NR **Sessions:** 12 **Frequency (number of doses per week):** 1 **Duration (weeks):** 12 **Provider:** Trained yoga instructor **Control intervention** **Name:** Waitlist control **Description:** The waitlist control group participated in tai chi/yoga classes at the end of the tai chi/yoga treatment period. The yoga and waitlist control groups were the same size and followed the same weekly schedule **Format:** Individual **Group size:** N/A **Sessions:** NR **Frequency (number of doses per week):** NR **Duration (weeks):** 12 **Provider:** NR
Outcomes	**Outcomes used:** CED-S, STAI, sleep disturbance, leaving study early **Outcomes not used:** N/A
Study design	Randomised controlled trial (RCT)
Source of funding	NIH grant (HD056036) and a Senior Research Scientist Awards (AT001585)

	and funding from Johnson & Johnson Pediatric Institute to the Touch Research Institute
Limitations	
Notes	

1.39.6 MANBER2004

Study ID	MANBER2004
Bibliographic reference	Manber R, Schnyer RN, Allen JJB, Rush JA, Blasey CM. Acupuncture: a promising 13 treatment for depression during pregnancy. Journal of Affective Disorders. 2004; 14 83:89-95.
Methods	**Blinding of participants:** Yes (for the acupuncture groups but not massage group) **Blinding of personnel:** Yes (for the acupuncture groups but not massage group) **Blinding of outcome assessment:** Self-report **Setting:** **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** HRSD 21.0 (4.2), did not differ significantly between the groups **N (number randomised):** 61 **Mean age (years):** 33 **Risk factor/s:** N/A **Inclusion criteria**: i) 18 years or older; ii) gestation age between 11 and 28 weeks at screening; iii) be receiving prenatal care in the community; iv) satisfy DSM-IV criteria for current nonpsychotic Major Depressive Episode (MDE); v) score at least 14 on the 17-item Hamilton Rating Scale for Depression **Exclusion criteria:** i) An index MDE lasting 2 years or more; ii) psychotic features or a seasonal pattern; iii) current active suicidal potential; iv) cluster B Axis II disorder or other Axis I disorders in the past 2 months, except for simple phobia, social phobia, or generalized anxiety disorder [determined by the SCID-IV; v) abnormal thyroid panel; vi) an uncontrolled medical condition, a condition that may be a medical basis for depression; vii) current use of any medication that impacts mood; viii) confounding treatments for depression; ix) conditions that necessitate bed rest.
Interventions	**Experimental intervention** **Name:** Depression specific acupuncture **Description:** Acupuncture treatments did not consist of a fixed set of points. Instead, treatments were individually tailored following the principles of traditional Chinese medicine. The assessment, treatment design, needle insertion, and needle stimulation were all standardized. Each SPEC and NSPEC treatment consisted of the same number of acupuncture points distributed across the same general areas of the body. **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** 2 **Duration (weeks):** 8 **Provider:** Acupuncturist **Control Intervention (1)**

	Name: Non-depression specific acupuncture **Description:** Acupuncture treatments did not consist of a fixed set of points. Instead, treatments were individually tailored following the principles of traditional Chinese medicine. The assessment, treatment design, needle insertion, and needle stimulation were all standardized. Each SPEC and NSPEC treatment consisted of the same number of acupuncture points distributed across the same general areas of the body. **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** 2 **Duration (weeks):** 8 **Provider:** Acupuncturist **Control Intervention (2)** **Name:** Massage **Description:** Massage was provided in a standardised fashion for the same frequency and duration and included minimal verbal contact **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** 2 **Duration (weeks):** 8 **Provider:** Massager
Outcomes	**Outcomes used:** HRDS, BDI, DSM criteria, response **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	Agency of Health Research and Quality grant # HS09988.
Limitations	1. Unclear risk of selection bias 2. Unclear risk of attrition bias
Notes	For the purpose of the review, a comparions is made between depression specific acupuncture and non-depression specific acupuncture. A comparison is also made between acupuncture (both types combinded) and massage.

1.39.7MANBER2010

Study ID	MANBER2010
Bibliographic reference	Manber R, Schnyer RN, Lyell D, Chambers AS, Caughey AB, Druzin M et al. 16 Acupuncture for depression during pregnancy: a randomized controlled trial. 17 Obstetrics and Gynecology. 2010;115:511-20.
Methods	**Blinding of participants:** Yes (for the acupuncture groups but not massage group) **Blinding of personnel:** Yes (for the acupuncture groups but not massage group) **Blinding of outcome assessment:** Self-report **Setting:** **Country:** US
Participants	**Timing:** Antenatal **Baseline symptoms:** HRSD: Depression specfic acupuncture 21.5 (3.8); non-depression specific acupuncture 20.3 (3.6); massage 20.4 (3.6). **N (number randomised):** 150 **Mean age (years):** 33 **Risk factor/s:** N/A **Inclusion criteria**: i) Between 12 and 30 weeks of gestation; ii) 18 years or older; iii) Meet criteria for major depressive disorder according to the (DSM-IV-TR), determined by the Structured Clinical Interview for the DSM-IV,and score at least 14 on the 17-item Hamilton Rating Scale for Depression **Exclusion criteria:** i) other current primary Axis I psychiatric disorders, except social phobia;ii) seasonal affective disorder or psychotic features; iii) abnormal thyroid panel or drug screen results; iv) serious uncontrolled medical conditions or conditions that may be a medical basis of depression; v) cluster B personality disorders (determined by the Structured Clinical Interview for DSM-IV interview for Axis II disorders); vi) current psychotherapy, herbs, or psychotropic medications; vii) electroconvulsive therapy or vagal nerve stimulation in the past year; viii) current active suicidal potential necessitating immediate treatment; ix) absence of prenatal care; and x) conditions necessitating bed rest.
Interventions	**Experimental intervention** **Name:** Depression specific acupuncture **Description:** Acupuncture specific for depression was tailored individually to address each participant's depression related patterns of disharmony according to the principles of traditional Chinese medicine and following a published standardized treatment manual **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** two times per week for the first 4 weeks and weekly for 4 more weeks. **Duration (weeks):** 8 **Provider:** Acupuncturist **Control Intervention (1)** **Name:** Non-depression specific acupuncture **Description:** Acupuncture not specific for depression was also standardized and needles were inserted in real acupuncture points that did not address depression-relevant patterns of disharmony according to traditional Chinese medicine. The manual for standardized acupuncture not specific for

	depression is available on request. Points needled varied by person and bytreatment week, and points that are either forbidden or advised for use with caution during pregnancy were excluded. Seven to 12 points were needled in each session and were distributed across the same general areas of the body for both treatments **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** two times per week for the first 4 weeks and weekly for 4 more weeks. **Duration (weeks):** 8 **Provider:** Acupuncturist **Control Intervention (2)** **Name:** Massage **Description:** Acupuncture not specific for depression was also standardized and needles were inserted in real acupuncture points that did not address depression-relevant patterns of disharmony according to traditional Chinese medicine. The manual for standardized acupuncture not specific for depression is available on request. Points needled varied by person and bytreatment week, and points that are either forbidden or advised for use with caution during pregnancy were excluded. Seven to 12 points were needled in each session and were distributed across the same general areas of the body for both treatments **Format:** Individual **Group size:** N/A **Sessions:** 12 **Frequency (number of doses per week):** two times per week for the first 4 weeks and weekly for 4 more weeks. **Duration (weeks):** 8 **Provider:** Massage therapist
Outcomes	**Outcomes used:** Response. **Outcomes not used:** side effects; Data could not be extracted for continuous data (HRDS, BDI)
Study design	Randomised controlled trial (RCT)
Source of funding	Agency for Health Research and Quality Grant award HS09988.
Limitations	1. Unclear risk of attrition bias
Notes	For the purpose of the review, a comparions is made between depression specific acupuncture and non-depression specific acupuncture. A comparison is also made between acupuncture (both types combinded) and massage. Protocol registered: NCT00186654 Requested following information/data: Means and standard deviations for all outcomes at all time points (week 4 and 8)- the Hamilton Rating Scale for Depression. Clarification on the number of participants who dropped out of the study. No reply from author

1.39.8 O'HIGGINS2008

Study ID	O'HIGGINS2008
Bibliographic reference	O'Higgins M, St. James Roberts I, Glover V. Postnatal depression and mother and 37 infant outcomes after infant massage. Journal of Affective Disorders. 2008;109:189-92.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** **Setting:** **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** EPDS: Massage: 13.19 (3.84); Support 12.81 (4.98) **N (number randomised):** 62 **Mean age (years):** NR **Risk factor/s:** N/A **Inclusion criteria**: i) mothers on the postnatal ward who were willing to receive a questionnaire about their mood when their baby was one month old; ii) Mothers scoring above 12 on the EPDS **Exclusion criteria: i)** a recorded history of a psychotic disorder; ii) were under 17 years of age; iii) did not speak sufficient English or had housing or social difficulties necessitating contact with a social worker.
Interventions	**Experimental intervention** **Name:** Baby massage classes **Description:** The 1 h infant massage classes were run by trained members of the International Association of Infant Massage. Each class began with a group discussion and then focussed on different massage strokes demonstrated by the instructors on dolls. The emphasis was on paying attention to infant cues and responding appropriately so different massage strokes and amounts of massage would happen for each mother–infant pair and in each class. **Format:** Group **Group size:** NR **Sessions:** 6 **Frequency (number of doses per week):** NR **Duration (weeks):** NR **Provider:** trained massage therapists **Control Intervention** **Name:** Support group **Description:** The support group was set up specifically for the research project and was run by an experienced research team member. The 1 h groups were open-ended with no defined start or end session. Numbers attending ranged from 2 to 6 per week as not all mothers on the register were able to attend each week. Practical help with telephone helpline numbers and information on benefit entitlements was given. **Format:** Group **Group size:** NR **Sessions:** 6 **Frequency (number of doses per week):** NR **Duration (weeks):** NR **Provider:** Experienced research team member
Outcomes	**Outcomes used:** EPDS, SSAI

	Outcomes not used: ICQ-fussy/difficult scale; maternal sensitivity in interaction; infant performance in interaction; overall interaction
Study design	Randomised controlled trial (RCT)
Source of funding	Foundation for Integrated health
Limitations	1. High risk of performance bias
Notes	Author emails for following data: All means and standard deviations at all time points, details of randomisation, clarification on the number of participants analysed at each time point for each outcome measure. Full thesis with additional data provided

1.39.9 ONOZAWA2001

Study ID	ONOZAWA2001
Bibliographic reference	Onozawa K, Glover V, Adams D, Modi N, Kumar RC. Infant massage improves 17 mother-infant interaction for mothers with postnatal depression. Journal of Affective 18 Disorders. 2001;63:201-7.
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** **Setting:** **Country:** UK
Participants	**Timing:** Postnatal **Baseline symptoms:** median = 15.5 EPDS **N (number randomised):** 33 **Mean age (years):** 34 **Risk factor/s:** N/A **Inclusion criteria**: i) Primiparous mothers; ii) aged 18-45 years; iii) singleton born from 37 to 42 weeks gestation **Exclusion criteria:** i) Gross congenital abnormalities; ii) requiring admission to a special care baby unit
Interventions	**Experimental intervention** **Name:** Infant massage group + support group **Description:** Infant massage instruction for new parents. Instructors teach the techniques of infant massage by encouraging parents to observe and respond to their infants' body language and cues and adjust their touch accordingly. Participants also attended support group **Format:** Group **Group size:** NR **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 5 **Provider:** Trained instructor **Control Intervention** **Name:** Social support group **Description:** Informal group discussion of practical parenting problems and coping strategies. **Format:** Group

	Group size: NR **Sessions:** 5 **Frequency (number of doses per week):** 1 **Duration (weeks):** 5 **Provider:** Researcher
Outcomes	**Outcomes used:** EPDS **Outcomes not used:** Assessment of mother-child interaction on video
Study design	Randomised controlled trial (RCT)
Source of funding	NR
Limitations	1. High risk of attrition bias 2. High risk of performance bias
Notes	Authors supplied mean and SD for endpoint EPDS (only median and 95% CI reported in the paper)

1.39.10 WIRZ-JUSTICE2011

Study ID	WIRZ-JUSTICE2011
Bibliographic reference	Wirz-Justice A, Bader A, Frisch U, Stieglitz RD, Alder J, Bitzer J, et al. A Randomised, Double-Blind, Placebo-Controlled Study of Light Therapy for Antepartum Depression. Focus on Women's Mental Health. 2011;72:986-993
Methods	**Blinding of participants:** Non-blind (it was not possible to blind the participants) **Blinding of personnel:** Non-blind (it was not possible to blind the personnel) **Blinding of outcome assessment:** **Setting:** **Country:** Switzerland
Participants	**Timing:** Antenatal **Baseline symptoms:** Baseline SIGH-ADS-29, brightlight (27.9)6.3), dim light (27.5 (4.7). Baseline HDRS, bightlight (17.8) **N (number randomised):** 46 **Mean age (years):** 32 **Risk factor/s:** N/A **Inclusion criteria**: i) 18-45 years of age; German speaking; medically healthy; normal ocular function; 4 through 32 weeks gestation based on first trimester ultrasound; DSM-IV diagnosis of major depressive disorder; Structured Interview Guide for the HDRS with Atypical Depression Supplement (SIGN-ADS) score >=20; and ability to provide informed consent. **Exclusion criteria:** DSM-IV diagnoses of bipolar I or II disorder, seasonal affective idorder, any psychotic episode, substance abuse within the last 6 months, primary anxiety disorder, recent history of suicide attempt (6 months), delayed sleep phase disorder or hypersomnia with habitual sleep onset later than 1 AM or wakening later than 9 AM, and obstetric care or medications for medical disorders that might confound treatment results, fetal malformations, and intrauterine fetal death.

Interventions	**Experimental intervention** **Name:** Light therapy **Description:** Participants were asked to maintain their habitual bedtime and wake-up time and not to change it for study entry. Light treatment was planned to commence within 10-minutes of habitual wake-up time. The light box could be conveniently transported and set up by pregnant women . During the 5 week treatment period in their homes, sunjects sat in front of the light box daily for 60 minutes at a specified distance that provided an active dose of 7,000 lux red light (3.0 x 10lux.min) **Format:** Individual **Group size:** N/A **Sessions:** daily for 5 weeks **Frequency (number of doses per week):** 7 **Duration (weeks):** 5 **Provider:** N/A **Control Intervention** **Name:** Placebo **Description:** The same treatment as control, however the placebo was a 70 lux red light (3.0 x 10 lux.min) **Format:** Individual **Group size: N/A** **Sessions:** daily for 5 weeks **Frequency (number of doses per week):** 7 **Duration (weeks):** 5 **Provider:** N/A
Outcomes	**Outcomes used:** **Outcomes not used:**
Study design	Randomised controlled trial (RCT)
Source of funding	
Limitations	1. High risk of selective reporting bias (Paper reports additional outcomes which were not pre-specified in the protocol (MADRS, BDI)
Notes	

1.40PHYSICAL INTERVETIONS: TREATMENT – EXCLUDED STUDIES

Study	Reason for exclusion
Corral M, Wardrop AA, Zhang H, Grewal AK, Patton S. Morning light therapy for postpartum depression. Archives of Women's Mental Health. 2007;10:211-224	Less than 10 per arm
Da Costa D, Lowensteyn I, Abrahamowicz M, Ionescu-Ittu R, Drista M, Rippen N. A randomized clinical trial of exercise to alleviate postpartum depressed mood. Journal of psychosomatic obstetrics and gynaecology. 2009;30: 191-200.	Data could not be extracted- no means and standard deviations
Dritsa M, Costa D, Dupuis G, Lowensteyn I, Khalifé S. Effects of a home-based exercise intervention on fatigue in postpartum depressed women: Results of a randomized controlled trial. Annals of Behavioral Medicine. 2008;35:179-187	No mental health outcomes
Field T, Deeds O, Diego M, Hernandez-Reif M, Gauler A, Sullivan S, Benefits of combining massage therapy with group interpersonal psychotherapy in prenatally depressed women.Journal of Bodywork and Movement Therapies. 2009;13: 297-303.	Data could not be extracted- number of participants in each intervention arm not reported
Field T, Diego M, Hernandez-Reif M, Medina L, Delgado J, Hernandez A. Yoga and massage therapy reduce prenatal depression and prematurity. Journal body Movements Therapy. 2012;16:204-209	Data could not be extracted- number of participants in each intervention arm not reported
Field T, Figueiredo B, Hernandez-Reif M, Diego M, Deeds O, Ascencio A. Massage therapy reduces pain in pregnant women, alleviates prenatal depression in both parents and improves their relationships. Journal of Bodywork and Movement Therapies. 2008;12: 146-150.	Data could not be extracted- number of participants in each intervention arm not reported
Heh SS, Huang LH, Ho SM, Fu YY, Wang LL. Effectiveness of an exercise support program in reducing the severity of postnatal depression in Taiwanese women. Birth. 2008;35:60-65	Not an RCT
Mitchell J, Field T, Diego M, Bendell D, Newton R, Pelaez M. Yoga reduces prenatal depression symptoms. Psychology. 2012;3:782–6	Data could not be extracted- number of randomised participants (n=24) who completed follow up for each group was not reported
Myczkowski ML, Dias AM, Luvisotto T, Arnaut D, Bellini BB, Mansur CG, et al. Effects of repetitive transcranial magnetic stimulation on clinical, social, and cognitive performance in postpartum depression. Neuropsychiatric Disease and Treatment. 2012;8:491-500	Less than 10 per arm
Surkan PJ, Gottlieb BR, McCormick MC, Hunt A, Peterson KE. Impact of a health promotion intervention on maternal depressive symptoms at 15 months postpartum. Maternal and child health journal. 2012;1:139-148	Data cannot be extracted- Mean difference reported. SD not reported.