

National Institute for Health and Care Excellence

Consultation draft

Depression in adults: treatment and management

Appendix U2.8: Text from CG90 Appendix 17b that has been deleted

NICE Guideline

Appendices

May 2018

Disclaimer

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

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Appendix 17b: clinical studies characteristics tables – psychological and psychosocial interventions

Contents

| | |
|--|----|
| Computerised cognitive behavioural therapy (CCBT) – studies in the previous guideline and the update..... | 1 |
| Guided self-help – studies in previous guideline..... | 7 |
| Guided self-help – new studies in the guideline update..... | 13 |
| Physical activity programmes – studies in previous guideline..... | 20 |
| Physical activity programmes – new studies in the guideline update..... | 25 |
| Cognitive behavioural therapies – studies in previous guideline..... | 36 |
| Cognitive behavioural therapies – new studies in the guideline update..... | 50 |
| Cognitive behavioural therapies versus therapies designed for depression – new studies in the guideline update | 57 |
| Group cognitive behavioural therapies – new studies in the guideline update..... | 58 |
| Cognitive behavioural therapies – elderly – new studies in the guideline update..... | 61 |
| Cognitive behavioural therapies – relapse prevention – new studies in the guideline update..... | 62 |
| Cognitive behavioural therapies – mindfulness – relapse prevention – new studies in the guideline update..... | 65 |
| Group cognitive behavioural therapies – relapse prevention – elderly – new studies in the guideline update..... | 67 |
| Behaviour therapy (BT) – studies in previous guideline..... | 68 |
| Behaviour therapy/behavioural activation – new studies in the guideline update..... | 69 |
| Problem solving – studies in previous guideline..... | 71 |
| Problem solving – studies excluded in the guideline update..... | 73 |
| Couples therapy – studies in previous guideline..... | 74 |
| Couples therapy – new studies in the guideline update..... | 77 |
| Interpersonal therapy (IPT) – studies in previous guideline..... | 79 |

| | |
|--|-----|
| Interpersonal therapy - new studies in the guideline update..... | 83 |
| Interpersonal therapy - relapse prevention - studies excluded from the guideline update..... | 87 |
| Interpersonal therapy - elderly - maintenance - new studies in the guideline update..... | 88 |
| Interpersonal therapy - elderly - new studies in the guideline update..... | 89 |
| Counselling - studies in previous guideline..... | 90 |
| Counselling - new studies in the guideline update..... | 92 |
| Psychological interventions in older adults - studies in previous guideline..... | 94 |
| Short-term psychological treatments - studies in previous guideline..... | 94 |
| Short-term psychodynamic psychotherapy - studies in previous guideline..... | 95 |
| Short-term psychodynamic psychotherapy - new studies in the guideline update..... | 97 |
| Short-term psychodynamic psychotherapy - relapse prevention - new studies in the guideline update..... | 101 |
| Rational emotive behavioural therapy - new studies in the guideline update..... | 102 |
| Studies included in previous guideline and excluded in the guideline update..... | 103 |

Please note that references for studies from the previous guideline are in Appendix 18.

Computerised cognitive behavioural therapy (CCBT) - studies in the previous guideline and the update

Comparisons Included in this Clinical Question

CCBT + postcard reminders vs CCBT + phone reminders vs control

CLARKE2005

CCBT vs control

CLARKE2002

PROUDFOOT2004A

CCBT vs group CBT vs wait list control

SPEK2007

CCBT vs psychoeducation website vs control

CHRISTENSEN2004A

CCBT vs therapist CBT vs wait list control

SELMI1990

CCBT vs wait list control

ANDERSSON2005A

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|---|---|---|
| ANDERSSON2005A Study Type: RCT Type of Analysis: completers Blindness: Open Duration (days): Mean 70 Followup: 6 months Setting: Press release & newspaper ads; Sweden Notes: RANDOMISATION: carried out by independent person who drew numbers from bowl Info on Screening Process: 343 | n= 117 Age: Mean 36 Sex: 30 males 87 females Diagnosis: 100% Major depression by CIDI-SF Exclusions: score below 15 or above 30 on MADRS, psychosis, bipolar disorder, antidepressant medication begun/changed in last 6 months, history of CBT, <18 years, not prepared/able to work with self-help programme Notes: Diagnosis is based on self report via computer, participants were included if they had probability of 0.55 or more of major depression diagnosis and MADRS-S total score of 15-30. Baseline: CCBT Control BDI (21 item) 20.5 (6.7) 20.9 (8.5) MADRS-S (9 item) 20.1 (5.7) 21.6 (7.2) | Data Used Leaving study early for any reason MADRS-S (9 item) BDI (21 item) Data Not Used QoL - not relevant BAI (21 items) - not relevant Notes: All measures self reported via computer. | Group 1 N= 57 CCBT - 5 modules available on website, each module ended with quiz, responses were automatically sent to therapist who gave email feedback & access to next module within 24 hours. Mean time for completion was 10 weeks. Online discussion group - Treatment group could discuss contents of self-help material etc. Activity in discussion groups was closely monitored Group 2 N= 60 Wait list - no treatment Online discussion group - Control group discussed topics such as sick leave & experience of being depressed. Activity in discussion groups was closely monitored | Funding: L.J. Boethius Foundation & Swedish Research Council. |

Results from this paper:

ANDERSSON2004 is 6 month follow-up, by this time participants in control group had also received treatment. Paper reports pre-treatment predictors of improvement following CCBT. BERSTROM2003 is a poster of this study.

| | | | | |
|--|--|---|--|---|
| CHRISTENSEN2004A Study Type: RCT Type of Analysis: ITT Blindness: Open Duration (days): Mean 42 Followup: 6 months & 1 year Setting: recruitment via questionnaire; Australia Notes: RANDOMISATION: procedure not reported Info on Screening Process: 27000 | n= 525 Age: Mean 36 Sex: 150 males 375 females Diagnosis: No formal diagnosis Exclusions: refused to participate, uncontactable, language difficulty, unwilling to be randomised etc. Notes: No diagnoses given but participants scored 12 or above on Kessler psych distress scale. Baseline: CCBT Psychoeducation Control Kessler 17.9 (5.0) 17.5 (4.9) 18.0 (5.7) CES-D 21.8 (10.5) 21.1 (10.4) 21.6 (11.1) | Data Used Leaving study early for any reason CES-D Data Not Used Goldberg Anxiety scale - not relevant Goldberg Depression scale - not relevant CBT literacy - not relevant Lifestyle literacy - not relevant Psychological literacy - not relevant Medical literacy - not relevant Automatic thoughts Questionnaire - not relevant | Group 1 N= 182 CCBT - MoodGYM website: 5 20-40 minute online modules, lay interviewers phoned participants weekly to direct use of website & give overview at 6 weeks. Group 2 N= 165 Online psychoeducation - BluePages: psychoeducation website, lay interviewers phoned participants weekly to direct use of website & give overview at 6 weeks. Group 3 N= 178 Control - 'attention placebo' lay interviewers phoned participants weekly to discuss lifestyle factors eg exercise, education & health habits | Funding: National Health & Medical Research Council Australia programme grant to the Centre for Mental Health Research. |
|--|--|---|--|---|

Results from this paper:

CHRISTENSEN2004 & CHRISTENSEN2006E: compare participants in MoodGYM arm of this trial to community visitors of the MoodGYM website.

GRIFFITHS2004: effects of MoodGYM & BluePages on reducing stigma.

CHRISTENSEN2006D: 6-month follow-up, investigates subsequent help seeking for specific treatments.

MACKINNON2008: 6 & 12-month outcomes of trial.

CHRISTENSEN2006C: compares 6 versions of MoodGYM.

| | | | | |
|-------------------|---|---------------------------|---|--|
| CLARKE2002 | <p>n= 223 Age: Mean 44 Sex: 55 males 168 females</p> <p>Diagnosis: 75% Depression 25% No formal diagnosis</p> <p>Exclusions: no exclusion criteria other than all participants were members of health maintenance organisation & had internet access</p> <p>Notes: Data is given only for 75% (N=223) of sample who had received medical services in previous 30 days in association with recorded diagnosis of depression. Other 25% of sample were non-depressed adults (not extracted).</p> <p>Baseline: CCBT Control CES-D 30.7 (12.9) 31.3 (11.5)</p> | Data Used CES-D | <p>Group 1 N= 107 CCBT - Overcoming Depression on the Internet: interactive CCBT website focussing on cognitive restructuring techniques, participants sent email reminders to return to the website at 4, 8, 16 & 32 weeks post randomisation.</p> <p>Group 2 N= 116 Control - directed to webpage where users can obtain non-interactive info re. health concerns including depression, can ask nurse/pharmacist or request appointment at medical centre; participants sent email reminders to return to website at 4, 8, 16 & 32 weeks.</p> | Funding: partly funded by grant from Garfield Foundation Depression Initiative Project |
| CLARKE2005 | | | | |

| | | | | | | | | | | | | | |
|---|---|---|---|---|----------|-----------|--|-------------------|-------------|-------------|--------------------------------------|--|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Open</p> <p>Duration (days): Mean 112</p> <p>Setting: recruitment brochures mailed to members of health maintenance organisation; US</p> <p>Notes: RANDOMISATION: by random sequence software</p> <p>Info on Screening Process: 12051</p> | <p>n= 200</p> <p>Age: Mean 47</p> <p>Sex: 46 males 154 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 78% Depression 22% No formal diagnosis <p>Exclusions: no exclusion criteria other than all participants were members of health maintenance organisation & had internet access</p> <p>Notes: 200 participants (78% of total sample) had received treatment for depression in previous 30 days & had chart diagnosis of depression. Data extracted only for this depressed subset of sample.</p> <p>Baseline:</p> <table border="0"> <tr> <td>CCBT</td> <td>CCBT</td> <td>TAU</td> </tr> <tr> <td>postcard</td> <td>telephone</td> <td></td> </tr> <tr> <td>CES-D 31.4 (11.8)</td> <td>31.3 (13.4)</td> <td>28.8 (13.6)</td> </tr> </table> | CCBT | CCBT | TAU | postcard | telephone | | CES-D 31.4 (11.8) | 31.3 (13.4) | 28.8 (13.6) | <p>Data Used</p> <p>CES-D</p> | <p>Group 1 N= 54</p> <p>CCBT + postcard reminders - Overcoming Depression on the Internet: interactive website training in cognitive restructuring, no behaviour therapy techniques employed, participants sent postcard reminders to return to the website at 2, 8, & 13 weeks post randomisation.</p> <p>Group 2 N= 67</p> <p>CCBT + telephone reminders - Overcoming Depression on the Internet: interactive website training in cognitive restructuring, no behaviour therapy employed, participants telephoned by non-clinical staff & reminded to return to the website at 2, 8, & 13 weeks post randomisation.</p> <p>Group 3 N= 79</p> <p>Control - directed to health maintenance organisation website which provides information about depression</p> | <p>Funding: grant from Garfield Foundation Depression Initiative Project, authors are independent of funding agency.</p> |
| CCBT | CCBT | TAU | | | | | | | | | | | |
| postcard | telephone | | | | | | | | | | | | |
| CES-D 31.4 (11.8) | 31.3 (13.4) | 28.8 (13.6) | | | | | | | | | | | |
| <p>PROUDFOOT2004A</p> <p>Study Type: RCT</p> <p>Type of Analysis: completers</p> <p>Blindness: Open</p> <p>Duration (days): Mean 63</p> <p>Followup: 2, 3, 5, 8 months</p> | <p>n= 274</p> <p>Age: Mean 44</p> <p>Sex: 72 males 202 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 27% Mixed anxiety/depression by ICD-10 | <p>Data Used</p> <p>Leaving study early for any reason</p> <p>BDI</p> <p>Data Not Used</p> <p>HRSD minus sleep items - not relevant</p> <p>Sustained response - not relevant</p> <p>Work & Social Adjustment - not relevant</p> | <p>Group 1 N= 146</p> <p>CCBT - Beating the Blues: 15 minute introductory video followed by 8 therapy sessions approximately 50 minutes each, 1 session a week. Carried out at GP clinic, practice nurse checked patients at beginning & end of session. (N=56 in depression-only group)</p> | <p>Funding: NHS Executive London Research & Development Responsive Funding Programme & by Ultrasis UK Ltd.</p> <p>2</p> | | | | | | | | | |

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|---|---|---|---|--|
| Notes: RANDOMISATION: randomly sorted cards Info on Screening Process: 502 | <p>24% Mixed anxiety/depression mild by ICD-10</p> <p>12% Severe depressive episode by ICD-10</p> <p>16% Moderate depressive episode by ICD-10</p> <p>5% Mild depressive episode by ICD-10</p> <p>5% Panic disorder by ICD-10</p> <p>4% Social phobia by ICD-10</p> <p>3% At least 2 major depressive episodes by ICD-10</p> <p>2% Specific phobia by ICD-10</p> <p>Exclusions: <18 or >75 years, receiving psychological intervention, score <4 on GHQ-12, score <12 on computerised version of Clinical Interview Schedule-Revised, suicidal ideas, psychotic disorder, organic mental disorder, alcohol/drug dependency, taking medication for anxiety/depression continuously for >6 months prior to trial, unable to read/write English, unable to attend sessions</p> <p>Notes: pre-treatment data for 24 patients lost due to human error; outcome data used are for 92 patients with depression only supplied by authors. NB: percentages for each diagnosis type do not add up to 100%.</p> <p>Baseline: CCBT TAU BDI 24.9 (10.8) 24.7 (9.2)</p> | <p>BAI - not relevant</p> <p>Notes: Available at endpoint and 3-, 5-, and 8-month follow-up</p> | <p>Group 2 N= 128</p> <p>Control - TAU: whatever treatment is prescribed by GP (N=36 in depression-only group)</p> | |
|---|---|---|---|--|

Results from this paper:

PROUDFOOT2003 reports 1st phase of this trial (with less participants)

| | | | | | | | | | | | | |
|-----------------------|--|-----|------|-------------------|--------------|------------------|--------------|-----------------------|--------------|--|---|--|
| Selmi1990 | <p>n= 36</p> <p>Age: Mean 28</p> <p>Sex: 13 males 23 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 69% Major depression by RDC 11% Minor depressive disorder by RDC 19% Intermittent depressive disorder by RDC <p>Exclusions: SCL-90-R depression score below the 65th percentile for psychiatric outpatients, BDI <16</p> <p>Baseline:</p> <table border="0"> <tr> <td>BDI</td> <td>HRSD</td> </tr> <tr> <td>CCBT 21.42 (3.96)</td> <td>14.33 (4.01)</td> </tr> <tr> <td>CBT 23.18 (7.19)</td> <td>15.09 (4.55)</td> </tr> <tr> <td>Waitlist 22.92 (5.02)</td> <td>15.57 (5.00)</td> </tr> </table> | BDI | HRSD | CCBT 21.42 (3.96) | 14.33 (4.01) | CBT 23.18 (7.19) | 15.09 (4.55) | Waitlist 22.92 (5.02) | 15.57 (5.00) | <p>Data Used</p> <p>HRSD BDI Leaving study early for any reason</p> <p>Data Not Used</p> <p>Automatic thoughts Questionnaire - not relevant SCL-90-R (global symptoms) - not relevant SCL-90-R (depression) - not relevant</p> | <p>Group 1 N= 12</p> <p>CBT CCBT - 6 sessions once a week, programme assessed symptoms & functioning, checked patients' understanding of material & gave feedback, prepared homework assignment; experimenter present at start & end of session and available to answer questions</p> <p>Group 2 N= 12</p> <p>Therapist CBT - 6 sessions once a week with trained advanced graduate student who followed treatment manual, session agendas identical to computer programme</p> <p>Group 3 N= 12</p> <p>Wait list - no treatment for 14 weeks</p> | |
| BDI | HRSD | | | | | | | | | | | |
| CCBT 21.42 (3.96) | 14.33 (4.01) | | | | | | | | | | | |
| CBT 23.18 (7.19) | 15.09 (4.55) | | | | | | | | | | | |
| Waitlist 22.92 (5.02) | 15.57 (5.00) | | | | | | | | | | | |
| SPEK2007 | | | | 9 | | | | | | | | |

| | | | | |
|---|---|---|---|--|
| Study Type: RCT | n= 301 | Data Used Leaving study early for any reason BDI (21 item) Data Not Used CIDI - not relevant NEO-FFI - not relevant EDS (10 item) - not relevant Notes: Leaving study early is no. of participants who did not complete post treatment measures. | Group 1 N= 102 CCBT - self-help internet based intervention with 8 modules, consisting of text, exercises, videos & figures, covers same subjects as CWD course, no professional support offered (carried out at home) Group 2 N= 99 Group CBT - Coping with Depression course: 10 weekly group sessions on psychoeducation, cognitive restructuring, behaviour change & relapse prevention, groups consisted of no more than 10 participants Group 3 N= 100 Wait list - no treatment | Funding: grant from ZON-MW, Netherlands Organisation for Health Research & Development |
| Type of Analysis: ITT Blindness: Open Duration (days): Mean 70 Followup: 1 year Setting: recruited by ads in regional newspapers & letters sent by Municipal Health Care Service; Netherlands Notes: RANDOMISATION: random allocation sequence generated Info on Screening Process: 606 | Age: Mean 55 Sex: 110 males 191 females Diagnosis: 100% No formal diagnosis Exclusions: score < 12 on EDS, DSM-IV diagnosis of depression, aged <50 or >75, refusal to give informed consent, no access to internet, inability to use internet, psychiatric disorder in immediate need of treatment, suicidal ideation. Notes: no compliance with DSM-IV diagnosis of depression but participants scored >12 on EDS Baseline: CCBT group CBT Control BDI 19.17 (7.21) 17.89 (9.95) 18.13 (8.10) | | | Results from this paper: SPEK2008 reports 1 year follow-up. SPEK2008A reports on which participant characteristics predict outcome for CCBT & group CBT. |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|------------------|---|
| BOWERS1993 | Less than 10 participants in each condition |
| CUKROWICZ2007 | Non-clinical population |
| DEGRAAF2008 | Protocol only - no data available |
| ELGAMAL2007 | Not CCBT - reports RCT for computer assisted cognitive retraining programme, no depression outcomes reported. |
| HETHERTON2004 | Abandoned RCT, no data reported |
| OSGOOD-HYNES1998 | Non-RCT |
| TREBO2007 | Paper does not report enough information regarding intervention, BDI data illegible in table |
| VAN STRATEN2008 | General population |
| WARMERDAM2008 | Protocol-only available; data published but not available on UCL ejournals (only published electronically); emailed author for copy |
| WHITFIELD2006 | Non-RCT |
| WRIGHT2005A | GDG did not consider the intervention provided was the same as CCBT provided in the NHS (it focused on CCBT augmentation of a therapist-delivered intervention) |

References of Included Studies

- ANDERSSON2005A (Published Data Only)
Berstrom, J., Hollandare, F., Carlbring, P., Kaldo-Sandstrom, V., Ekselius, L., & Andersson, G. (2003) Treatment of depression via the internet: A randomized trial of a self-help programme. Journal of Telemedicine and Telecare, 9, S2: 85.

Andersson, G., Bergstrom, J., Hollandare, F., Ekselius, L., & Carlbring, P. (2004) Delivering cognitive behavioural therapy for mild to moderate depression via the internet: Predicting outcome at 6-month follow-up. *Verhaltenstherapie*, 14, 185-189.

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CHRISTENSEN2004A (Published Data Only)

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- Christensen, H., Griffiths, K. M., Mackinnon, A. J., & Brittcliffe, K. (2006) Online randomized controlled trial of brief and full cognitive behaviour therapy for depression. *Psychological Medicine*, 36, 1737-1746.
- Mackinnon, A., Griffiths, K. M., & Christensen, H. (2008) Comparative randomised trial of online cognitive-behavioural therapy and an information website for depression: 12-Month outcomes. *British Journal of Psychiatry*, 192, 130-134.
- Christensen, H., Griffiths, K., Groves, C., & Korten, A. (2006) Free range users and one hit wonders: community users of an Internet-based cognitive behaviour therapy program. *Australian & New Zealand Journal of Psychiatry*, 40, 59-62.
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CLARKE2002 (Published Data Only)

- Clarke, G., Reid, E., Eubanks, D., O'Connor, E., DeBar, L. L., Kelleher, C. et al. (2002) Overcoming Depression on the Internet (ODIN): A randomized controlled trial of an internet depression skills intervention program. *Journal of Medical Internet Research*, 4, e14.

CLARKE2005 (Published Data Only)

- Clarke, G., Eubanks, D., Reid, E., Kelleher, C., O'Connor, E., DeBar, L. L. et al. (2005) Overcoming depression on the internet (ODIN) (2): A randomized trial of a self-help depression skills program with reminders. *Journal of Medical Internet Research*, 7, e16.

PROUDFOOT2004A (Unpublished and Published Data)

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- *Proudfoot, J., Ryden, C., Everitt, B., Shapiro, D. A., Goldberg, D., Mann, A. et al. (2004) Clinical efficacy of computerised cognitive-behavioural therapy for anxiety and depression in primary care: randomised controlled trial. *British Journal of Psychiatry*, 185, 46-54.

Selmi1990 (Published Data Only)

- Selmi, P.M., Klein, M.H., Greist, J.H., Sorrell, S.P., Erdman, H.P. (1990) Computer-administered cognitive behavioral therapy for depression. *American Journal of Psychiatry*, 147(1), 51-56.

SPEK2007 (Published Data Only)

- Spek, V., Nyklicek, I., Cuijpers, P., & Pop, V. (2008) Predictors of outcome of group and internet-based cognitive behavior therapy. *Journal of Affective Disorders*, 105, 137-145.
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CUKROWICZ2007 (Published Data Only)

- Cukrowicz, K.C., Joiner,T.E.Jr (2007) Computer-based intervention for anxious and depressive symptoms in a non-clinical population. *Cognitive Therapy & Research*, 31, 677-693.

DEGRAAF2008

(Published Data Only)

de Graaf, L.E., Gerhards, S.A., Evers, S.M., Arntz, A., Riper, H., Severens, J.L., Widdershoven, G., Metsemakers, J.F., Huibers, M.J. (2008). Clinical and cost-effectiveness of computerised cognitive behavioural therapy for depression in primary care: Design of a randomised trial. *BMC Public Health*, 8 (224), 1-11.

ELGAMAL2007

(Published Data Only)

Elgamal, S., McKinnon, M. C., Ramakrishnan, K., Joffe, R. T., & Macqueen, G. (2007) Successful computer-assisted cognitive remediation therapy in patients with unipolar depression: a proof of principle study. *Psychological Medicine*, 37, 1229-1238.

5

HETHERTON2004 (Published Data Only)

Hetherton, J., Matheson, A., & Robson, M. (2004) Recruitment by GPs during consultations in a primary care randomized controlled trial comparing computerized psychological therapy with clinical psychology and routine GP care: Problems and possible solutions. *Primary Health Care Research and Development*, 5, 5-10.

OSGOOD-HYNES1998 (Published Data Only)

Osgood-Hynes, D. J., Greist, J. H., Marks, I. M., Baer, L., Heneman, S. W., Wenzel, K. W. et al. (1998) Self-administered psychotherapy for depression using a telephone-accessed computer system plus booklets: an open U.S.-U.K. study. *Journal of Clinical Psychiatry*, 59, 358-365.

TREBO2007 (Published Data Only)

Trebo, E., Holzner, B., Pircher, M., Prunnlechner, R., Gunther, V. (2007) The effects of a computer assisted cognitive training on neuropsychological parameters, mood and dysfunctional cognitions in depressive patients. *Neuropsychiatrie*, 21, 207-215.

VAN STRATEN2008 (Published Data Only)

Van Straten, A., Cuijpers, P., Smits, N. (2008) Effectiveness of a web-based self-help intervention for symptoms of depression, anxiety, and stress: Randomized controlled trial. *Journal of Medical Internet Research*, 10,1.

WARMERDAM2008 (Published Data Only)

Warmerdam, L., van Straten, A., Twisk, J., Riper, H., Cuijpers, P. (2008) Internet-based treatment for adults with depressive symptoms: randomized controlled trial. *Journal of Medical Internet Research*. 10(4), e.44

Warmerdam, L., van Straten, A., & Cuijpers, P. (2007) Internet-based treatment for adults with depressive symptoms: The protocol of a randomized controlled trial. *BMC Psychiatry*, 7, 72.

WHITFIELD2006 (Published Data Only)

Whitfield, G., Hinshaw, R., Pashely, A., Campsie, L. & Williams, C. (2006) The impact of a novel computerised CBT CD rom (Overcoming Depression) offered to patients referred to clinical psychology. *Behavioural and Cognitive Psychotherapy*, 34, 1-11.

WRIGHT2005A (Published Data Only)

Wright, J. H., Wright, A. S., Albano, A. M., Basco, M. R., Goldsmith, L. J., Raffield, T. et al. (2005) Computer-assisted cognitive therapy for depression: maintaining efficacy while reducing therapist time. *American Journal of Psychiatry*, 162, 1158-1164.

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Guided self-help - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|-------|---------|--------------|---------------|----------|-------|----|
|-------|---------|--------------|---------------|----------|-------|----|

| | | | | | | |
|-------------|---|--|---|---|--|---|
| Beutler1991 | <p>Allocation: random (no details)</p> <p>Duration: 20 weeks +3-month follow-up.</p> <p>Analysis: Patients who remained in treatment for at least 4 sessions (LOCF)</p> | <p>Outpatients with moderate depression, recruited via press, word of mouth & professional recommendation who were willing to discontinue all other pharmacological or psychological treatments. N=76, 5 patients were excluded after it was found they had not withdrawn from other mental health treatments therefore study analysis was based on 71 patients, mean age = 46.76. 67%</p> | <p>1. Group CBT - following Yost et al (1986) and Beck et al (1979)</p> <p>2. Focused expressive psychotherapy - a Gestalt-based group psychotherapy supplemented by homework assignments</p> <p>3. Supportive self-directed therapy - weekly telephone contacts of 30 minutes each and reading prescribed books. Group size - 5 - 10 members</p> | <p>1. BDI mean scores at endpoint</p> <p>2. BDI mean scores at 3-month follow-up</p> <p>3. HRSD mean scores at endpoint</p> <p>4. HRSD mean scores at 3-month follow-up</p> | <p>Therapists were 4 experienced psychologists trained in CT and focused expressive psychotherapy. Five advanced graduate students conducted supportive self-directed therapy.</p> | B |
|-------------|---|--|---|---|--|---|

| | | | | | | |
|------------|---|---|--|--|--|---|
| | | female. Diagnosis: DSM-III major depressive disorder and HRSD>=16 | | | | |
| Bowman1995 | Allocation: random Duration of study: 4 weeks + 2-month follow-up assessment. Analysis: completer | Included community-dwelling individuals who scored >=10 on HRSD-21, were not in psychotherapy at the time of the study, not receiving pharmacotherapy and not evidencing or reporting psychosis, suicidal risk or mania N = 32; mean age 36.2 years, 62.5% female Diagnosis: HRSD>=10 | 1. Cognitive bibliotherapy: Participants received "Feeling Good" (Burns, 1980). Participant received weekly calls from a researcher to evaluate progress and to offer help in interpreting anything about the book which was unclear. 2. Self-examination therapy: Participants received a 39-page booklet which encouraged participants to isolate themselves at home for at least 30 minutes each week to decide what was relevant to their lives and record this on a sheet. The book suggested using a flow-chart format to attempt to address their difficulties. The book encouraged discarding problems that did not matter to them and to brainstorm for solutions for problems that did matter to them. 3. Wait list control: Participants received weekly calls from researchers assuring them that treatment would become available. Following 4 weeks waiting-period, were randomised to either of the first two treatments (data extracted for 4 week study period only). | 1. HRSD mean scores at endpoint 2. HRSD mean scores at 2 month follow-up (interventions 1 and 2 only) 3. BDI mean scores at endpoint 4. BDI mean scores at 2-month follow-up (interventions 1 & 2 only) 5. Leaving the study early | Country of study: US Two participants who dropped out before post-treatment assessment were replaced. | B |
| Brown1984 | Allocation: Random Duration: 8 weeks + 1 month & 6-month follow-ups. Analysis: ITT | Individuals responding to an announcement for "Coping with Depression". N = 80; Study analyses were based on a subsample of 63 participants who met RDC criteria for unipolar depression, mean age 36.5 years (range 16-65 years); 70% female Diagnosis: SADS-RDC diagnosis: major depressive (44% patients) disorder, minor depressive disorder (11% patients), intermittent depressive disorder (44% patients) | 1. Class psychoeducation (or group bibliotherapy): Two classes of nine in the first cohort and 2 classes of 7 in the second cohort. Classes were co-taught by 2 instructors. Lecturing supplemented course readings and homework assignments were reviewed. Participants were asked to share experiences in doing homework. Cohesiveness among participants was promoted. Duration of session: 2 hours. 2. Individuals psychoeducation (or individual bibliotherapy): Similar to class condition, but consisted of individual tutoring sessions. Duration of sessions: 50 minutes or less. 3. Telephone contact: Instructors met with participants for one session at beginning of course during which rationale of course was elaborated upon and assignments and monitoring forms explained. All subsequent sessions were conducted via telephone | 1. BDI mean scores at endpoint 2. BDI mean scores at 1 month and 6-month follow-up (interventions 1, 2 & 3 only) 3. Non-remitters (patients still meeting SADS-RDC criteria for depression) at 6-month follow-up (interventions 1, 2 & 3 only) | Country of study: US. Of 63 participants with unipolar depression, 22 were involved in concurrent treatment for depression at the time of initial assessment. Four advanced doctoral students in Clinical Psychology served as instructors. Following the intake interview, participants met with their instructor | B |

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| | | | <p>contacts during which participants were encouraged and assisted in completing course assignments. Calls lasted 15 minutes.</p> <p>4. Wait list control: Following 8-week waiting period, participants received class psychoeducation (data extracted for 8 week study period only)</p> <p>The course employed "Control your depression" (Lewinsohn et al, 1978). A participant workbook (Brown & Lewinsohn, 1984) was developed that contained goal statements and assignments for each unit. Three weeks per session were held during first 4 weeks and one per session during second 4 weeks. Skill areas taught in the course were learning how to relax, increasing pleasant activities, changing aspects of one's thinking, and improving social skills and increasing positive social interactions</p> | | <p>during which instructors became acquainted with participant and presented overview and rationale of the course.</p> | |
| Jamison1995 | <p>Allocation: Random (no details)</p> <p>Duration of study: 4 weeks treatment phase plus 3-month follow-up</p> <p>Analysis: completer</p> | <p>Outpatients N = 80; Mean age: 40 years; 84% female. Diagnosis: HRSD-21 \geq 10; DSM for mild or moderate major depression - responses to HRSD were examined and determined whether five of nine symptoms required by DSM-III R were present, including depressed mood or loss of interest or pleasure; BDI \geq 10 Brief screening interview conducted to find out willingness to read a book as the major treatment</p> | <p>1. Cognitive bibliotherapy: Patients were requested to read "Feeling Good" (Burns, 1980) within 4 weeks, and given, a booklet describing exercises in the book. BDI administered by weekly telephone interviews. Number of exercises were noted at successive interviews.</p> <p>2. Wait list control: During 4-week waiting period, BDI administered during 10-minute telephone interviews. Received bibliotherapy at end of 4 weeks (data extracted for 4 week study period only).</p> | <p>1. Leaving the study early</p> <p>2. HRSD mean endpoint scores</p> <p>3. BDI mean endpoint scores</p> <p>4. Non-remitters (patients not achieving HRSD \leq 12)</p> <p>5. Non-remitters (patients not achieving BDI \leq 11)</p> | <p>Country of study: US</p> <p>3-month follow-up data not extracted since control group received bibliotherapy during follow-up interval</p> | B |
| Landreville 1997 | <p>Allocation: Random (no details)</p> <p>Duration of study: 4 weeks + 6-month follow-up</p> <p>Analysis: completer</p> | <p>Volunteers through media, practitioners, and social service professionals (a) aged \geq 55 years; (b) Geriatric Depression Scale \geq 11; (c) having one or more disabilities in activities of daily life; (d) living independently in the community</p> <p>N = 44; study analyses were based on a subsample of 23</p> | <p>1. Cognitive Bibliotherapy: Participants received a copy of "Feeling Good" (Burns, 1980) and asked to read entire book within 4 weeks. An average of 46.66% (range 6.66 to 100%) of the book was read.</p> <p>2. Wait list control: These participants received 4-week bibliotherapy after the study treatment phase (data extracted for 4 week study period only).</p> <p>Participants in both groups received 15-minute telephone calls once a week by a graduate psychology student in order to assess progress and answer questions about the book in the experimental group, and to</p> | <p>1. BDI mean endpoint scores</p> | <p>Country of study: Canada</p> | B |

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| | | <p>patients who had depression diagnosis and who completed the study (number of patients with diagnosis of depression originally randomised not given) ; mean age: Bibliotherapy (N=10) 71.8 years; Control (N=13) 72.15 years; 87% female. 63.63% had physical problems Diagnosis: DSM-III-R for major depression (N = 17) or DSM-IV for minor depression (N = 6)</p> | <p>monitor condition and to encourage them to persevere until treatment became available in the control group.</p> | | |
| Schmidt 1983 | <p>Allocation: Random</p> <p>Duration of study: 8 weeks treatment phase + 10-week follow-up</p> <p>Analysis: ITT</p> | <p>Individuals with BDI ≥ 10, depression as major presenting problem, with a minimum duration for the current episode of 2 weeks, no history of bipolar symptomatology or other psychotic states, absence of suicidal ideation during prior year and absence of suicidal behaviour during past 2 years, payments of a \$25 research deposit. N = 56; mean age 42 years; 84% female. Diagnosis: Study conducted shortly before publication of DSM-III and RDC for affective disorders. Retrospective analysis revealed multiple items pertinent to determination of all RDC criteria except "distinct quality of depressed mood". Based on this , 5 participants had endogenomorphic depression.</p> | <p>1. Bibliotherapy: Clients met in two small groups with therapist during first week of treatment. Clients received a copy of the self-help manual and were asked to return mood assessment forms every week. The self-help manual was based on "Control your depression" (Lewinsohn et al, 1986), Beck (1976), Alberti & Emmons (1970), and Lange & Jakubowski (1976). Clients received a telephone call during the 4th week aimed at encouraging and answering the client's questions.</p> <p>2. Individual therapy,</p> <p>3. Small group therapy, and</p> <p>4. Large group therapy: Clients met with therapist weekly for 90 minutes. Treatment procedures and ways of dealing with client's difficulties were discussed. Earlier sessions concentrated on behavioural methods. Cognitive materials followed, presenting more difficult and introspective assignments. Finally assertion skills were taught by combining introspective and behavioural tasks.</p> <p>5. Wait list controls: Clients were informed that they would receive therapy in about 8 weeks (data extracted for 8 week study period only).</p> | <p>1. Leaving the study early</p> <p>2. BDI mean scores at endpoint</p> <p>3. BDI mean scores at 10-week follow-up (interventions 1, 2, 3 & 4 only)</p> | <p>Country of Study: US</p> <p>D</p> |
| Scogin 1987 | <p>Allocation: Random (no details)</p> <p>Duration of study: 4 week</p> | <p>Community-dwelling individuals aged ≥ 60 years who could read.</p> <p>N = 29; mean age: Cognitive bibliotherapy, 70.8 years, WLC;</p> | <p>1. Cognitive bibliotherapy: Participants received a copy of "Feeling Good" (Burns, 1980).</p> <p>2. Wait list control: Following 1-month waiting period, participants received cognitive bibliotherapy (data extracted for 4 week study period only).</p> | <p>1. Leaving the study early</p> <p>2. BDI mean endpoint scores</p> <p>3. HRSD mean</p> | <p>Country of study: US</p> <p>B</p> <p>3 in cognitive bibliotherapy and 1 in WLC were receiving medication</p> <p>13</p> |

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| | treatment + 1-month follow-up. Analysis: completer | 71.8 years; control bibliotherapy, 68.5 years; 79% female Diagnosis: HDRS >= 10 | All participants undergoing therapy received 10-minute weekly phone calls from researchers that were supportive and involved an informal assessment of the participant's progress. Participants were encouraged to complete the book within one month 3. Control bibliotherapy: Participants received a copy of "Man's Search for Meaning" (Frankl, 1959). This treatment group started midway through the study in an effort to improve study design. Therefore, not properly randomised. Data not extracted for this treatment. | endpoint scores | prescribed by their physicians | |
| Scogin 1989 | Allocation: random (no details) Duration of study: 1 month + 6-month follow-up. Analysis: completer | Community-dwelling individuals aged >=60 years recruited via the media. N = 67; mean age 68.3 years; 85% female Diagnosis: HDRS >= 10; Mental Status Questionnaire >=8 | 1. Cognitive Bibliotherapy: Participants received a copy of "Feeling Good" (Burns, 1980) 2. Behavioural Bibliotherapy: Participants received a copy of "Control your Depression" (Lewinsohn et al, 1986) 3. Wait list control: At the end of waiting period, participants were randomised to either cognitive or behavioural bibliotherapy (data extracted for 4 week study period only) All participants receiving bibliotherapy received 5-minute weekly telephone calls to assess progress and to answer questions about the reading material. Data was extracted for 1 and 3 only. | 1. Leaving the study early 2. HRSD mean scores at endpoint | Country of Study: US | B |

Characteristics of excluded studies

| Study | Reason for exclusion |
|----------------|--|
| Blenkiron 2001 | Not an RCT |
| Donnan 1990 | Patients did not have a primary diagnosis for depression |
| Hannay 1999 | Study on General Practitioner's views on introducing therapeutic writing to patients in the practice. Not an RCT |

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|-----------------|---|
| Holdsworth 1996 | Patients not diagnosed against recognised classification system |
| Kiely 1986 | Sample did not consist of patients with depression, but consisted of those presenting with psychological problems in which stress played a part |
| Robinson 1997 | No extractable data |
| Sorby 1991 | Patients were diagnosed with DSM-III panic disorder. Only 12% patients diagnosed with DSM-III MD, 8% with dysthymia. |

12

Guided self-help - new studies in the guideline update

Comparisons Included in this Clinical Question

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| Bibliotherapy vs expressive writing vs journaling vs supportive group vs group CBT STICE2007 | Bibliotherapy vs individual cognitive psychotherapy vs waitlist control FLOYD2004 | Minimal contact psychotherapy vs TAU control WILLEMSE2004 | Psychoeducation Contactus programme vs TAU control HANSSON2008 |
| Psychoeducational workshop vs waitlist control BROWN2004 | Self-help vs control GEISNER2006 | Self-help vs TAU control LOVELL2008 SALKOVSKIS2006 WILLIAMS2008 | |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|--|--|---|-------|
| BROWN2004 Study Type: RCT Type of Analysis: ITT Blindness: No mention Duration (days): Mean 1 Followup: 3 months Setting: recruited through ads at health centres, leisure centres, community centres & libraries; UK Notes: RANDOMISATION: using computerised random numbers by a researcher not who was not part of the clinical team. Info on Screening Process: 134 attended introductory talk | n= 120 Age: Sex: 23 males 111 females Diagnosis: 100% No formal diagnosis Exclusions: no exclusion criteria. Notes: N sex is for 134 people who attended talk, 35% participants between 35-44 but no other age information. No formal diagnosis, but 15% BDI 0-9, 30% BDI 10-18, 36% BDI 19-29, 19% BDI 30-63. Outcome data for those with BDI > 14 (exp n=30; control n=25). Baseline: BDI: psychoeducation 20.67 (10.93), control 19.3 (10.1) | Data Used BDI Leaving study early for any reason Data Not Used STA1 - not relevant Rosenberg self-esteem scale - not relevant GHQ-12 - not relevant Notes: Baseline assessment at introductory talk two to three weeks prior to workshop, outcome measures reported at 3-month follow-up. | Group 1 N= 60 Psychoeducational workshop - 1 day (9.30am-4.30pm) self-confidence workshop for up to 25 people, run at leisure centre by 2 clinical psychologists & 2 assistant psychologists. CBT techniques were adapted for an educational programme. Group 2 N= 60 Wait list | |
| FLOYD2004 Study Type: RCT Type of Analysis: completers Blindness: Single blind Duration (days): Range 28-84 Followup: 3 months Setting: recruited through newspaper ads, TV, flyers, talks at senior citizen activity centres; US Notes: RANDOMISATION: procedure not reported. 1 rater not blind to treatment condition but sample of their interviews reviewed by blind assessor Info on Screening Process: 111 | n= 46 Age: Mean 68 Sex: 11 males 35 females Diagnosis: 100% MDD or minor depression or dysthymia by DSM-IV Exclusions: <60 years, life-threatening illness, unable to read, concurrent treatment except antidepressants, thought disorders, bipolar disorder, alcoholism or substance dependence, suicide risk, cognitive impairment, score >=8 on Mental Status Questionnaire, score <10 on HRSD Notes: 26% participants currently on antidepressants Baseline: HRSD: bibliotherapy 17.12 (5.43), individual psychotherapy 16.62 (5.25), waitlist 16.36 (5.09) | Data Used Leaving study early for any reason HRSD Data Not Used Brief symptom inventory - not relevant Geriatric depression scale - not relevant | Group 1 N= 16 Bibliotherapy - participants asked to read Feeling Good (Burns 1980) book and complete all homework exercises in 1 month. Participants were telephoned weekly to monitor adherence. Group 2 N= 16 Individual psychotherapy - 12-20 sessions of cognitive therapy, 2 sessions/week for 1st 4 weeks, then weekly sessions for 8-12 weeks, therapists were trained clinical psychology graduate students, therapy lasted 12 weeks. Group 3 N= 14 Wait list - for 4 weeks, participants were phoned weekly, after 4 weeks were randomly assigned to one of the treatment conditions | |
| GEISNER2006 | | | | 29 |

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|--|---|---|--|-------------------------------|
| <p>Study Type: RCT</p> <p>Type of Analysis: completers</p> <p>Blindness: No mention</p> <p>Duration (days):</p> <p>Followup: 1month</p> <p>Setting: students recruited from university's psych departments mass testing subject pool, received course credits for participation; US</p> <p>Notes: RANDOMISATION: determined by computerised random number generator</p> <p>Info on Screening Process: 1166</p> | <p>n= 177</p> <p>Age: Mean 19</p> <p>Sex: 53 males 124 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% No formal diagnosis <p>Exclusions: >18 years, score <14 BDI</p> <p>Baseline: BDI: self-help 18.81 (7.43), control 18.28 (7.09)</p> | <p>Data Used</p> <ul style="list-style-type: none"> Leaving study early for any reason BDI <p>Data Not Used</p> <ul style="list-style-type: none"> Hopelessness scale - not relevant Self-Help scale - not relevant | <p>Group 1 N= 89</p> <ul style="list-style-type: none"> Self-help - participants received personalised feedback & a brochure listing strategies for coping with depressive symp by mail 1 week after baseline assessment <p>Group 2 N= 88</p> <ul style="list-style-type: none"> Control - participants received brief letter thanking them for participation & a list of resources in the community after baseline assessment | |
| <p>HANSSON2008</p> <p>Study Type: RCT</p> <p>Type of Analysis: completers</p> <p>Blindness: No mention</p> <p>Duration (days): Mean 42</p> <p>Setting: recruited from 46 primary health care centres across Sweden</p> <p>Notes: RANDOMISATION: cluster randomisation - each primary health care centre randomised to intervention or control</p> | <p>n= 319</p> <p>Age: Mean 44</p> <p>Sex: 87 males 232 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Depression by GP <p>Exclusions: <18, >69 years, no diagnosis of depression, unsuitable for group participation</p> <p>Notes: Data reported only for 122 participants with HAD-D >10 at baseline, 81% participants on antidepressants, 9% concurrent psychotherapy</p> <p>Baseline: HAD-D: psychoeducation 9.2 (4.4), control 9.2 (4.4)</p> | <p>Data Used</p> <ul style="list-style-type: none"> HADS <p>Data Not Used</p> <ul style="list-style-type: none"> GAF-self - not relevant | <p>Group 1 N= 205</p> <ul style="list-style-type: none"> Psychoeducation - Contactus programme - lectures once a week & discussions after in groups 8-10 participants led by social worker or nurse characterised by support & sharing experiences <p>Group 2 N= 114</p> <ul style="list-style-type: none"> TAU | |
| <p>LOVELL2008</p> <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 84</p> <p>Setting: Primary care (GP and primary care mental health team referrals)</p> <p>Notes: RANDOMISATION: randomised, no details other than allocation minimised by age, gender and severity of depression</p> <p>Info on Screening Process: 148 screened; 53 did not meet inclusion criteria, 6 refused to participant, 30 not included for other reasons (not given); 59 randomised</p> | <p>n= 59</p> <p>Age: Mean 38</p> <p>Sex: 16 males 43 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Depression by GP <p>Exclusions: BDI-II < 14 or BDI-II > 28 (raised to 45 following recruitment problems); current psychological treatment, suicidal intent, postnatal depression, bereavement reaction, primary drug/alcohol dependence.</p> <p>Baseline: BDI-II 28.97 (8.3)</p> | <p>Data Used</p> <ul style="list-style-type: none"> BDI-II endpoint Leaving study early for any reason <p>Notes: BDI-II endpoint = mean endpoint data; outcomes at 3 months</p> | <p>Group 1 N= 29</p> <ul style="list-style-type: none"> Self-help - Guided self-help using Lovell K., Richards, D.A. A Recovery Programme for Depression (2007) Rethink. Based on CBT; designed to be delivered in 3-10 sessions over 5-12 weeks; (mean N sessions 3.5 (range 1-10)), 79.3% took antidepressants <p>Group 2 N= 30</p> <ul style="list-style-type: none"> TAU - Usual GP care; 58.6% took antidepressants | <p>SIGN 1+; funded by MRC</p> |
| <p>SALKOVSKIS2006</p> | | | | |

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|-----------------------|--------------|--|---|
| Study Type: RCT | n= 96 | Data Used BDI Leaving study early for any reason | Group 1 N= 50 Self-help - computer algorithm used to design sequence of individually tailored workbooks using information from questionnaire & subsequent assessments, most received about 6 modules & could request up to 3 additional standard booklets on diet, exercise etc TAU - as provided by GP, all participants prescribed antidepressants which were taken for a mean of 32.3 weeks |
| Type of Analysis: ITT | Age: Mean 40 | Data Not Used Satisfaction ratings - not relevant CarePartners scale - not relevant PGI - not relevant | |

Blindness: Open

Duration (days):

Followup: 4 weeks, 12 weeks & 6 months

Setting: recruited from 46 GPs; UK

Notes: RANDOMISATION: carried out independently using sealed envelopes prepared using random number tables, groups stratified

n= 96
Age: Mean 40
Sex: 19 males 77 females

Diagnosis:
100% Major depression by DSM-IV SCID

Exclusions: participants without depressive disorder, participants not prescribed antidepressants, informed consent not given, <17, >70 years, difficulty reading English, severe medical illness, psychosis, bipolar disorder, current

Data Used
BDI
Leaving study early for any reason

Data Not Used
Satisfaction ratings - not relevant
CarePartners scale - not relevant
PGI - not relevant

Group 1 N= 50
Self-help - computer algorithm used to design sequence of individually tailored workbooks using information from questionnaire & subsequent assessments, most received about 6 modules & could request up to 3 additional standard booklets on diet, exercise etc
TAU - as provided by GP, all participants prescribed antidepressants which were taken for a mean of 32.3 weeks

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| according to gender Info on Screening Process: 112 | longer than 4 weeks, BDI score <10 Baseline: BDI: self-help 27.5 (9.8), TAU 27.1 (10.5) | Notes: Production & day-to-day running of programme undertaken by CarePartners project. | Group 2 N= 46 TAU - as provided by GP, all participants prescribed antidepressants which were taken for a mean of 28.8 weeks | |
| STICE2007 Study Type: RCT Type of Analysis: ITT Blindness: No mention Duration (days): Mean 30 Followup: 6 months Setting: high school & college students recruited through mass mailings, emails & flyers; US Notes: RANDOMISATION: within blocks created by gender & school, group CBT & waitlist have more participants because other conditions added later | n= 225 Age: Mean 18 Range 15-22 Sex: 67 males 158 females Diagnosis: 100% No formal diagnosis Exclusions: CES-D score <20, BDI score >30 Baseline: BDI group CBT 20.58 (6.55) supportive group 19.95 (5.99) bibliotherapy 20.28 (5.78) expressive writing 18.15 (5.91) journaling 19.76 (6.80) waitlist 19.38 (5.98) | Data Used Leaving study early for any reason BDI | Group 1 N= 50 Group CBT - brief programme of 4 weekly 1 hour sessions facilitated by a trained clinical graduate student & undergraduate, groups of 6-10 participants, brief individual catch-up session given if participant missed a session, detailed manual used Group 2 N= 19 Supportive-expressive group - provides forum to discuss feelings, 4 weekly 1 hour sessions facilitated by a trained clinical graduate student & undergraduate, groups of 6-10 participants, brief individual catch-up session given if participant missed a session, detailed manual used Group 3 N= 28 Bibliotherapy - asked to read Feeling Good (Burns 1980) CBT approach to depression Group 4 N= 27 Expressive writing - asked to write about very deepest thoughts & feelings about an extremely important emotional issue that has affected them for 45 minutes 3 times over 3 weeks, writing sessions took place in a lab in a quiet private space Group 5 N= 34 Journaling - participants given a journal and asked to write during their free time and/or at least once a week, no further instructions given about writing Group 6 N= 67 Wait list - no treatment, offered group CBT at end of study | Supported by grants from the Hogg Foundation at the University of Texas and National Research Service Awards, and the National Institute of Health. |
| WILLEMSE2004 | | | | |

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| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 60</p> <p>Followup: 1 year</p> <p>Setting: recruited from 19 GPs across Netherlands</p> <p>Notes: RANDOMISATION: carried out centrally using blocked scheme stratified by GP with patient as unit of randomisation, with blocks of 4 patients</p> <p>Info on Screening Process: 3825</p> | <p>n= 216</p> <p>Age: Mean 41</p> <p>Sex: 73 males 143 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Subthreshold depression <p>Exclusions: <18 or >65 years, hearing or language difficulties, received treatment by mental health professional in last year or being on waiting list, life-threatening illness, learning disability, suicidal risk, psychotic symptoms, schizophrenia, dementia, meeting DSM-IV criteria for depressive disorder, dysthymia, bipolar disorder, social phobia, agoraphobia, panic disorder in last year</p> | <p>Data Used</p> <p>CES-D Leaving study early for any reason</p> <p>Data Not Used</p> <p>RAND-36 - not relevant CIDI - not relevant</p> | <p>Group 1 N= 107</p> <p>Minimal contact psychotherapy - based on CWD course, main component CBT self-help manual with exercises & homework assignments. Face-to face interview with clinician before reading manual & 6 short supportive phone calls (max 15 minutes) 1st 5 every 2 weeks & 6th call 2 months later</p> <p>Group 2 N= 109</p> <p>TAU - as provided by GP & other health service providers</p> |
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| | 1 core symptom + 1-3 current depressive symptoms according to Instel screening instrument Baseline: CES-D: minimal contact therapy 12.5 (8.4), TAU control 13.0 (8.5) | | | |
| WILLIAMS2008 Study Type: RCT Type of Analysis: completers & ITT Blindness: No mention Duration (days): Mean 120 Followup: 1 year Setting: referred from 7 GPs, Scotland Notes: RANDOMISATION: using automated remote telephone system Info on Screening Process: 541 | n= 281 Age: Mean 42 Sex: 89 males 192 females Diagnosis: 100% No formal diagnosis Exclusions: <18, BDI score <14, inability to use written materials, suicidal intent, impaired concentration or motivation, Notes: 58% participants currently/recently on medication Baseline: BDI-II: self-help 28.48 (8.75), TAU control 29.00 (9.34) | Data Used Improvement: change in BDI-II (clinical) BDI Leaving study early for any reason Data Not Used Satisfaction ratings - not relevant Euroquol - not relevant CORE - not relevant | Group 1 N= 141 Self-help - CBT 'Overcoming Depression: A 5 Areas Approach' 10 short workbooks which can be used in modular way so participant only works through books relevant to them, 3 40 minute sessions with psychology graduate, 4th session could be provided Group 2 N= 140 TAU - as provided by GP including medication, referral etc | |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|------------------|---|
| ALLARTVANDAM2003 | In CBT review |
| ANDERSON1986 | Only 57% with primary diagnosis of depression (other participants depressed with psychotic features, bipolar, BPD, schizoaffective etc) |
| BOWMAN1995 | Dropouts replaced |
| COCKRAM2002 | Not RCT |
| CRAVEN2005 | Not RCT |
| CUIJPERS2005C | Not RCT |
| DALGARD2006 | In CBT review |
| DEN BOER2007A | Not self-help |
| FLETCHER2005 | Only 19% of participants depressed (53% mixed anxiety & depression, 19% anxiety) |
| HANSER1994 | Dropouts replaced |
| HARINGSMA2006A | In CBT review |
| JACOB2002 | No diagnosis, not self-help |
| JORM2003 | No diagnosis, not self-help |
| KENDRICK2005 | Not self-help |
| LANG2006 | No relevant outcome measures |
| LARA2003D | Not RCT |
| LYNCH2004A | Not self-help |
| RICHARDS2003 | No diagnosis |
| SEIVEWRIGHT1998 | Only 31% participants diagnosed with dysthymia, 69% GAD or panic |
| TYRER1988 | No extractable data |
| WOLLERSHEIM1991 | Less than 10 participants in each condition |

References of Included Studies

- BROWN2004** (Unpublished and Published Data) 16
Brown, J. S., Elliott, S. A., Boardman, J., Ferns, J., & Morrison, J. (2004) Meeting the unmet need for depression services with psycho-educational self-confidence workshops: preliminary report. British Journal of Psychiatry, 185, 511-515.

FLOYD2004

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Floyd, M., Scogin, F., McKendree-Smith, N. L., Floyd, D. L. & Rokke, P. D. (2004) Cognitive Therapy for depression: A comparison of individual psychotherapy and bibliotherapy for depressed older adults. *Behavior Modification*, 28, 297-318.

GEISNER2006

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Geisner, I. M., Neighbors, C., & Larimer, M. E. (2006) A randomized clinical trial of a brief, mailed intervention for symptoms of depression. *Journal of Consulting & Clinical Psychology*, 74, 393-399.

HANSSON2008

(Published Data Only)

Hansson, M., Bodlund, O., Chotai, J. (2008) Patient education and group counselling to improve the treatment of depression in primary care: a randomized controlled trial. *Journal of Affective Disorders*, 105, 235-240.

LOVELL2008

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Lovell, K., Bower, P., Richards, D., Barkham, M., Sibbald, B., Roberts, C., Davies, L., Rogers, A., Gellatly, J., Hennessy, S. (2008) Developing guided self-help for depression using the Medical Research Council complex interventions framework: a description of the modelling phase and results of an exploratory randomised controlled trial. *BMC Psychiatry*, 8, 91-110.

SALKOVSKIS2006

(Published Data Only)

Salkovskis, P., Rimes, K., Stephenson, D., Sacks, G., & Scott, J. (2006) A randomized controlled trial of the use of self-help materials in addition to standard general practice treatment of depression compared to standard treatment alone. *Psychological Medicine*, 36, 325-333.

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Physical activity programmes - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|------------------|---|---|--|---|----------------------------------|----|
| Bosscher 1993 | Allocation: Random (no details) Duration: 8 weeks. Analysis: completer | Inpatients. N = 24; mean age: 34 years (range 18-52 years), 50% female Diagnosis: RDC for major or minor depression plus ≥ 40 on Zung Self-rating Depression Scale | 1.Short-term running therapy: Sessions were conducted 3 times a week, each lasting 45 minutes and consisted of a 10-minute warm-up phase of stretching exercises, a 30-minute running phase and a 5-minute cooling-down phase, which consisted of walking and repeated stretching exercises. Intensity of running was kept between 70 and 85% of maximum heart rate. There was | 1. Leaving the study early 2. Self-rating Depression Scale mean endpoint scores 3. Hopkins Symptom Checklist mean | Country of Study: Netherlands | B |

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|--------------|--|--|---|--|--|---|
| | | | <p>an emphasis on non-competitive running. After first 3 sessions, running was performed in small groups.</p> <p>2. Mixed exercise treatment: Sessions conducted 2 times per week each lasting 50 minutes and consisted of 10-minute warm-up phase, followed by 2 or 3 forms of physical exercise. A relaxed, low-intensity physical activity was emphasised. An extra weekly 45-minute session with relaxation and breathing exercises was conducted to equal the number of sessions per week with the other condition.</p> | endpoint scores | | |
| Fremont 1987 | <p>Allocation: Random</p> <p>Duration: 10 weeks + 2 months post-treatment assessment + 4 months follow-up assessment.</p> <p>Analysis: completer</p> | <p>Individuals experiencing problems with negative moods, not currently in therapy or taking antidepressant medication, not participating in regular aerobic exercise in the last 3 months.</p> <p>N = 61; based on 49 completers, age range 19 - 62, 73.5% female; 12 were college students and 37 community residents</p> <p>Diagnosis: BDI between 9 and 30</p> | <p>1. Running: participants met 3 times a week for 10 weeks with a running coach in groups of 6-8 at an indoor university track. Each session began with recording resting heart rate and a period of stretching exercises. Following programme guidelines by Cooper (1970), participants exercised for 20 continuous minutes. Coaching was provided by four experienced runners who supervised stretching exercises, gave instruction on running technique, provided encouragement and helped participants enjoy the experience.</p> <p>2. Cognitive therapy: 10 weekly 1-hour sessions provided by 17 therapists based on "Feeling Good" (Burns, 1980). Counsellor's role was to help client become aware of negative thought patterns and to change them to more positive ones.</p> <p>3. Combination: Participants received 10 cognitive therapy sessions plus 3-times-a-week running sessions.</p> | <p>1. Leaving the study early</p> <p>2. BDI mean scores at endpoint, 2 months follow-up and 4 months follow-up</p> | <p>Country of Study: US Since screening took place over 5 weeks, participants who left the study early were replaced with the next available participant</p> | B |
| Greist 1979 | <p>Allocation: Random (no details)</p> <p>Duration: 10 weeks. Analysis: completer</p> | <p>Inpatients and outpatients between 18 and 30 years. N = 28, 53.6% female.</p> <p>Diagnosis: RDC for minor depression and SCL-90 depression cluster score at 50th percentile or above</p> | <p>1. Running therapy: Initially, running leader met with patients 3-4 times per week for 1 hour. Running was done in small groups. During 5th week of treatment, only 2 sessions, and during 7th and 8th weeks, only one session. Patients were encouraged to run at least 3 times a week. During each session, leader ensured that patients ran and walked comfortably and taught them to use their breathing rate and ability to converse while running as feedback and guides to a comfortable pace. Pace and distance covered increased gradually and steadily as treatment progressed.</p> <p>2. Time-limited psychotherapy (no details)</p> <p>3. Time-unlimited psychotherapy (no details)</p> | <p>1. Leaving the study early</p> | <p>Country of study: US. Some of the therapists doing time-limited psychotherapy had failed to set clear time-limited contracts. Some of the psychotherapy was not as closely supervised as planned.</p> | B |

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|----------------|---|---|---|--|---|---|
| Herman 2002 | Allocation: Random (no detail), stratified by mild/moderate-severe symptoms. Raters were blind to participant's treatment allocation Duration: 16 weeks + 24 week follow-up. Analysis: ITT | Inpatients and outpatients; recruited through flyers, media advertisements and letters sent to local physicians and mental health facilities. N = 156; mean age: Exercise - 57 years +-5.8, Sertraline - 57 years +-7, Combination: 57 years +- 6.7; 73% female Diagnosis: DSM-IV for major depressive disorder and HRSD >= 13. Comorbid physical conditions included endocrine, cardiac, pulmonary and orthopaedic conditions | 1. Exercise: 3 supervised sessions per week. Participants were assigned individual training ranges equivalent to 70% to 85% of heart rate reserve. Each session began with a 10-minute warm-up period followed by 30 minutes of continuous walking or jogging at an intensity that would maintain heart rate within the assigned training range. The session concluded with 5 minutes of cool-down exercises. 2. Sertraline: Staff psychiatrist met with patient at study onset and weeks 2, 6, 10, 14 and 16. At meeting, psychiatrist evaluated treatment response and side effects and titrated dosage accordingly. Treatment was initiated at 50 mg and titrated up to 200 mg. Median dosage 100 mg. 48% of participants initiated an exercise program during the 6-month follow-up. 3. Combination: Patients received treatments 1 and 2. | 1. Leaving the study early 2. Leaving the study due to side effects 3. HRSD-17 mean endpoint scores 4. BDI-21 mean endpoint scores 5. Non-remitters (patients who met criteria for DSM-IV for MDD + HDRS >= 7 at endpoint) | Country of study: US. Follow-up data not extracted: some participants entered psychotherapy at the end of the study (Exercise: N = 7; sertraline: N = 7; combination: N= 8) | B |
| Klein1985 | Allocation: Random (no details) Duration: 12 weeks treatment + 1-, 3- and 9-month follow-up. Analysis: completer | Symptomatically depressed people from a Midwestern city who responded to a newspaper advertisement N = 74; mean age : running, 30.33 years (+-6.52), meditation, 29.96 (+- 6.29), group therapy, 29.75 (+-6.07); 72% female Diagnosis: RDC major or minor depression | 1. Running: Participants met individually with therapists in 2 45-minute sessions each week. Physical activity was divided into 2 segments, with 10-15 minutes of warm-up, followed by 30 minutes of aerobic walking/running. Participants were encouraged to run on their own between sessions and to complete weekly logs of physical activity. 2. Meditation-relaxation therapy: A range of breathing & yoga-based stretching exercises was used to help participant focus and control their breathing while achieving a deep state of relaxation. Periodic readings from meditation texts were interspersed with periods of silent sitting, yoga stretching exercises, and instructions on breathing. Homework assignments required participants to carry out exercises 2-3 times daily. 3. Group therapy: Included components of interpersonal and cognitive therapy. 2-hour weekly group meetings were held. | 1. Leaving the study early. 2. SCL-R (depression items only) mean scores at endpoint and 9 months follow-up. | Country of study: US | B |
| McCann 1984 | Allocation: random (no details) Duration: 10 weeks. Analysis: completer | Undergraduate women who enrolled in a general psychology course and had BDI>=11 N = 47 | 1. Aerobic exercise: Class met for 1 hour twice a week and also exercised outside the sessions. Aerobics involved dancing, jogging and running 2. Placebo: Subjects were given verbal and written instructions for the use of progressive muscle relaxation and were instructed to practise this 15-20 minutes a day 4 | 1. BDI mean endpoint scores 2. Leaving the study early | Country of study: US | B |

| | | | | | |
|----------------|--|--|---|---|----------------------------|
| | | | days per week preceded by a 5-minute leisurely walk. 3. No treatment (data not extracted). | | |
| McNeil 1991 | Allocation: random (no details) Duration: 6 weeks. Analysis: ITT | Community-dwelling depressed elderly individuals referred by community and religious organisations with no cognitive impairment (MMSE>=25), who were not currently receiving treatment for emotional problems and passed the Cooper 12-minute walk test. N = 30, mean age 72.5 years +-6.9. Diagnosis: BDI >=12 and <=24. | 1. Exercise: Participants walked outside their residence initially for 20 minutes per session and gradually for 40 minutes per session accompanied by the experimenter 2. Social contact: Consisted of two home visits per week by an undergraduate psychology student. Each visit consisted of casual conversation similar to that in exercise condition 3. Wait list condition | 1. BDI mean endpoint scores | Country of study: Canada B |
| Singh 1997 | Allocation: Random (no details); raters of outcome measures were blind to participant's treatment allocation Duration: 10 weeks phase I + 10 weeks phase II + 6 weeks' follow-up. Analysis: ITT | Outpatients, participants aged >= 60 years recruited from community through volunteer databases N = 32; mean age: exercise 70 years (+-1.5), control 72 years (+-2); 62.5% female Diagnosis: DSM-IV for major (41% patients) or minor (53%) depression or dysthymia (6%) and BDI > 12 | 1. Progressive resistance treatment: Phase I: Exercises included chest press, lattisimus dorsi pulldowns, leg press, knee extension and knee flexion. To maintain the intensity of the stimulus, load was increased at each session as tolerated by the subjects. Strength testing was repeated at 4 weeks to establish a new baseline value. Participants performed 3 sets of 8 repetitions on each machine. Each session lasted 45 minutes followed by 5 minutes of stretching. Frequency of sessions: 3 days per week for 10 weeks. Phase II: The group was offered 3 alternatives to continue training, (a) continue training at the facility on the resistance-training machines, (b) home-based training with free weights, (c) training at community health facility that provided resistance-training equipment. 2. Control: Phase I: Participants engaged in an interactive health education programme of lectures and videos followed by discussion. Frequency of sessions: 2 days a week for 1 hour. Phase II: There were no educational sessions, and subjects were given no exercise or other recommendations. | 1. BDI mean scores at endpoint, 20 weeks and 26 months 2. HRSD mean endpoint scores 3. Non-responders (patients not achieving >=50% reduction in HRSD) 4. Non-remitters (patients still meeting DSM-IV criteria for depression or dysthymia) at endpoint 5. Non-remitters (BDI<9) at 20 weeks | Country of study: US B |

| | | | | | | |
|---------------|---|--|--|--|----------------------------------|---|
| Veale 1992 | Allocation: Random in the ratio of 3:2 | Participants meeting inclusion criteria on Clinical Interview Schedule (CIS) and aged 18- 60 | 1. Aerobic exercise: 3 supervised sessions per weeks for 12 weeks in groups. Each session consisted of a warm-up routine and stretching exercises, followed by a running | 1. Leaving the study early 2. BDI mean endpoint | Country of study: Netherlands | B |
|---------------|---|--|--|--|----------------------------------|---|

23

| | | | | | | |
|--|---|--|---------------------------------------|--------|--|--|
| | Duration: 12 weeks. Analysis: completer | years. N = 83. 45% in exercise group and 34% in control group were prescribed antidepressants. Diagnosis: A total weighted score of ≥ 17 and a depression severity score of ≥ 2 on CIS | programme. 2. No treatment control | scores | | |
|--|---|--|---------------------------------------|--------|--|--|

Characteristics of excluded studies

| Study | Reason for exclusion |
|-----------|--|
| Blair1998 | Participants did not have depression, sample comprised community-dwelling adults who were patients of a primary healthcare setting |
| Doyne1987 | 22% of patients with RDC minor depression; number of participants randomised to each group not given |

| | |
|----------------------|--|
| Dunn2002 | Unable to extract any data. |
| Kritz-Silverstein 20 | Not a RCT; patients had heart disease |
| Labbe1988 | Patients not diagnosed with depression |
| Martinsen1989 | Fourteen patients in each group were administered tricyclic antidepressants during the study |
| Martinsen1993 | Not an RCT |

Physical activity programmes - new studies in the guideline update

Comparisons Included in this Clinical Question

| | | | |
|---|--|---|--|
| Aerobic exercise versus aerobic exercise + cognitive technique versus control BERLIN2003 | Aerobic exercise versus aerobic exercise + resistance exercise PASSMORE2006 | Different energy expenditure (low to 'public health') versus control DUNN2005 | High intensity weight training versus low intensity weight training versus GP care SINGH2005D |
| Home-based physical activity versus supervised physical activity versus antidepressant therapy versus placebo BLUMENTHAL2007 | Pharmacological therapy versus psychotherapy + physical activity PILU2007 | Physical activity + increased natural light exposure + vitamins vs placebo BROWN2001 | Physical activity versus control KNUBBEN2007 MATHER2002 SIMS2006 SINGH1997A TSANG2006 |
| Physical activity versus waitlist HABOUSH2006 | Supervised aerobic versus home-based aerobic versus sertraline versus placebo HOFFMAN2008 | Yoga versus health education BUTLER2008 | |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|-------------------------------|--|--------------------------------------|
| BERLIN2003 Study Type: RCT Type of Analysis: Completers Blindness: Open Duration (days): Mean 504 Setting: Referred by unit physician at adult psychiatric hospital; USA Notes: Participants completed the BDI themselves. Three intervention groups were rotated by the toss of a coin. No details of randomisation. Info on Screening Process: 94 referred. 44 were excluded. Reasons; declined participation in the study, discharged after the initial BDI but before completing the programme, changed their minds about participation, or removed from analysis due to excessively long length of stay. | n= 55 Age: Mean 40 Sex: 25 males 30 females Diagnosis: 100% No formal diagnosis Exclusions: Declined participation in the study, discharged after the initial BDI, but before completing the program, changed their minds about participation, or removed from analysis due to excessively long length of stay. Notes: Patients displayed depressive symptoms. Patients were included in the analyses if they had initial BDI scores of 14 or greater. Baseline: Aquatic Dual Control BDI 23.79 (7.0) 25.37 (8.3) 25.95 (12.0) | Data Used BDI change score | Group 1 N= 19 Physical activity - Once a week for 4 weeks. 10 minutes of unstructured warm up. 30 minutes of instructor-led pool exercise (water walking, upper body exercises, neck exercises, shoulder movements, lower body exercises, stretching and breathing moves & 5 minutes cool down) Group 2 N= 16 Physical activity with cognitive techniques - Once a week for 4 weeks. 10 minutes of cognitive techniques. 30 minutes of instructor-led pool exercise. 5 minutes of cognitive techniques. Content of cognitive sessions changed every week. Group 3 N= 20 Control - No intervention. | SIGN 1-; funding details not stated. |

| | | | |
|---|---------------------------|----------------|---|
| Results from this paper: | | | |
| Aquatic (N=19) | Dual (N=16) | Control (N=20) | |
| BDI Change | -11.15 (11.2) | -13.37 (2.3) | -5.25 (7.3) |
| BLUMENTHAL2007 | | | |
| Study Type: RCT | n= 202 | Data Used | Group 1 N= 51 |
| Study Description: Double-blind where pharmacological treatment used, otherwise single-blind. | Age: Mean 52 | HAM-D | Physical activity (supervised) - 3 times a week for 16 weeks - Aerobic exercise. 10 minute warm-up. 30 minutes of walking or jogging at ranges equivalent to 70-85% maximum heart rate reserve. 5 minutes |
| Type of Analysis: ITT; LOCF method | Sex: 49 males 153 females | | SIGN 1+; funded by Grant MH 49679 (JAB) from the National Institutes of Health ²⁵ and National Institutes of Health Grant MO1-RR-30 from the National Center for |
| | Diagnosis: | | |

| <p>Blindness: Double blind Duration (days): Mean 112</p> <p>Setting: Television, radio and newspaper advertisements; USA</p> <p>Notes: Parallel groups. Prescribed zolpidem for insomniac participants. Identifies early and late responders. Computer generated, conditional randomisation.</p> <p>Info on Screening Process: 457 patients screened. 255 excluded; 135 did not meet the criteria for MDD, 47 withdrew consent, 40 had an excluding psychiatric comorbidity, and 33 were ruled out for other reasons.</p> | <p>100% MDD or minor depression or dysthymia by DSM-IV SCID</p> <p>Exclusions: Presence of another primary psychiatric diagnosis, under 40 years of age, currently involved in regular exercise, currently involved in psychiatric treatment, medical comorbidities, current use of antidepressants or other psychotropic medications, dietary supplements or herbal therapies with purported psychoactive indications, current active alcohol or drug misuse or dependence, or active suicidal intent.</p> <p>Notes: Participants obtaining a BDI score either equal to or greater than 12 met the DSM-IV criteria for MDD and were recruited. MDD severity was assessed using the HAM-D.</p> <p>Baseline: BDI (21 item): 30.0 (8.0); Home = 31.0 (9.0); Sertraline = 30.0 (8.0); Placebo = 31.0 (8.0) HAM-D (17 item): Supervised = 16.0 (4.0); Home = 17.0 (5.0); Sertraline = 16.0 (4.0); Placebo = 17.0 (4.0)</p> | | <p>cool-down.</p> <p>Group 2 N= 53</p> <p>Physical activity (non-supervised) - 3 times a week for 16 weeks - Aerobic. Received initial home visit to establish training routine. 10 minute warm-up. 30 min walking or jogging at 70-85% maximum heart rate reserve. 5 minute cool-down.</p> <p>Group 3 N= 49</p> <p>Pharmacological therapy - 50-200mg daily - Sertraline provided by Pfizer, Inc. Dosage depended on clinical response. Usually each patient received a starting dose at 50mg and received increasing dosages to 200mg contingent on therapeutic response and presence of side effects.</p> <p>Group 4 N= 49</p> <p>Placebo - 50-200mg daily - Placebo provided by Pfizer, Inc. Received a starting dosage of 50mg and received increasing dosages to 200mg contingent on therapeutic response and presence of side effects.</p> | <p>Research Resources, Clinical Research Centers Program.</p> | | | | | | | | | | | | | | | |
|---|---|-------------|--|---|--|-------------------|-------------|-------------------|----------------|--------------|------------|------------|------------|------------|---------------|----------|----------|----------|----------|
| <p>Results from this paper:</p> <table> <thead> <tr> <th></th> <th>Supervised (N=51)</th> <th>Home (N=53)</th> <th>Sertraline (N=49)</th> <th>Placebo (N=49)</th> </tr> </thead> <tbody> <tr> <td>HAM-D Change</td> <td>-7.2 (6.9)</td> <td>-7.1 (6.9)</td> <td>-6.1 (6.7)</td> <td>-6.1 (7.3)</td> </tr> <tr> <td>Remission (N)</td> <td>23 (45%)</td> <td>21 (40%)</td> <td>23 (47%)</td> <td>15 (31%)</td> </tr> </tbody> </table> | | | | | | Supervised (N=51) | Home (N=53) | Sertraline (N=49) | Placebo (N=49) | HAM-D Change | -7.2 (6.9) | -7.1 (6.9) | -6.1 (6.7) | -6.1 (7.3) | Remission (N) | 23 (45%) | 21 (40%) | 23 (47%) | 15 (31%) |
| | Supervised (N=51) | Home (N=53) | Sertraline (N=49) | Placebo (N=49) | | | | | | | | | | | | | | | |
| HAM-D Change | -7.2 (6.9) | -7.1 (6.9) | -6.1 (6.7) | -6.1 (7.3) | | | | | | | | | | | | | | | |
| Remission (N) | 23 (45%) | 21 (40%) | 23 (47%) | 15 (31%) | | | | | | | | | | | | | | | |
| BROWN2001 | | | | | | | | | | | | | | | | | | | |

| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 56</p> <p>Setting: Mass media (particularly focussing on recruiting black communities); USA</p> <p>Notes: Randomised by independent consulting statistician. May not have been depressed.</p> <p>Info on Screening Process: No details given.</p> | <p>n= 112</p> <p>Age: Mean 43 Range 19-78</p> <p>Sex: 100 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% No formal diagnosis <p>Exclusions: Under the age of 18, significant chronic illness, taking medications which alter mood, mood scores below 11 or above 29 on the CES-D, current daily use of high doses of specified vitamins, aerobic exercise three or more times per week, physical disability that does not allow daily brisk walking, and regular participation in life activities which occur outdoors and exceed one hour a day.</p> <p>Notes: Used CES-D, POMS, General Well-Being, Rosenberg Self-Esteem and Depression Happiness scales.</p> <table border="1"> <thead> <tr> <th>Baseline:</th><th>Intervention</th><th>Control</th></tr> </thead> <tbody> <tr> <td>CES-D</td><td>19.0 (7.8)</td><td>22.2 (8.3)</td></tr> <tr> <td>Depression</td><td>46.3 (12.5)</td><td>40.7 (12.5)</td></tr> <tr> <td>POMS</td><td>64.0 (23.4)</td><td>79.1 (26.3)</td></tr> </tbody> </table> | Baseline: | Intervention | Control | CES-D | 19.0 (7.8) | 22.2 (8.3) | Depression | 46.3 (12.5) | 40.7 (12.5) | POMS | 64.0 (23.4) | 79.1 (26.3) | <p>Data Used</p> <p>Profile of mood states Rosenberg self-esteem scale CES-D</p> <p>Notes: Also used General Well-Being Schedule and Depression-Happiness Scale.</p> | <p>Group 1 N= 56</p> <p>Pharmacological therapy + physical activity - 5 days a week for 8 weeks - Brisk 20 minute outdoor walk during daylight hours at target heart rate of 60% of maximum heart rate. Also increased light exposure throughout the day and took a specific vitamin regimen. Also had one hour education session.</p> <p>Group 2 N= 56</p> <p>Control - Daily for 8 weeks - Received educational session about the mood-enhancing effects of vitamins. Given an 8 week supply of placebo vitamins to take daily.</p> | <p>SIGN 1-; funded in part by grants from The Center for Women's Research at the University of Washington (supported by National Institute for Nursing Research) and Psi Chapter of Sigma Theta Tau, Seattle, WA, a chapter of Sigma Theta Tau International, IN.</p> |
|--|---|--------------|--------------|---------|------------|-------------|----------------------|-------------|-------------|-------------|-------------|-------------|-------------|---|---|---|
| Baseline: | Intervention | Control | | | | | | | | | | | | | | |
| CES-D | 19.0 (7.8) | 22.2 (8.3) | | | | | | | | | | | | | | |
| Depression | 46.3 (12.5) | 40.7 (12.5) | | | | | | | | | | | | | | |
| POMS | 64.0 (23.4) | 79.1 (26.3) | | | | | | | | | | | | | | |
| <p>Results from this paper:</p> <table border="1"> <thead> <tr> <th></th> <th>Intervention</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>CES-D</td> <td>10.4 (7.3)</td> <td>16.7 (10.4)</td> </tr> <tr> <td>Depression Happiness</td> <td>58.8 (12.0)</td> <td>48.8 (14.1)</td> </tr> <tr> <td>POMS</td> <td>39.6 (22.5)</td> <td>60.4 (33.5)</td> </tr> </tbody> </table> | | Intervention | Control | CES-D | 10.4 (7.3) | 16.7 (10.4) | Depression Happiness | 58.8 (12.0) | 48.8 (14.1) | POMS | 39.6 (22.5) | 60.4 (33.5) | | | | 26 |
| | Intervention | Control | | | | | | | | | | | | | | |
| CES-D | 10.4 (7.3) | 16.7 (10.4) | | | | | | | | | | | | | | |
| Depression Happiness | 58.8 (12.0) | 48.8 (14.1) | | | | | | | | | | | | | | |
| POMS | 39.6 (22.5) | 60.4 (33.5) | | | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|-------------------|---|--------------|---|---------------------------------|---|--|--------------|--------------|--------------|---|---|---|
| BUTLER2008 | <p>Study Type: RCT Type of Analysis: Completers Blindness: No mention Duration (days): Setting: US Notes: RANDOMISATION: computer-generated random sequence</p> <p>n= 46 Age: Mean 50 Sex: 12 males 34 females</p> <p>Diagnosis: 50% Dysthymia by DSM-IV 28% Double depression by DSM-IV 15% MDD in partial remission by DSM-IV 7% Chronic major depression by DSM-IV</p> <p>Exclusions: Symptoms lasting <2 years; remission of 2 months or more in past 2 years; <18 years of age; not sufficiently proficient in English; unable to attend meetings; current bipolar disorder or psychotic features; psychosis; panic disorder; drug or alcohol dependence (past 3 months); suicidality; significant medical condition; current participation in individual or group psychotherapy or group meditation; started or recently changed prescribed antidepressant or St John's Wort (past 3 months)</p> <table border="0"> <tr> <td>Baseline:</td> <td>Meditation</td> <td>Hypnosis</td> <td>Control</td> </tr> <tr> <td>HRSD</td> <td>15.87 (7.29)</td> <td>12.33 (5.41)</td> <td>15.81 (8.01)</td> </tr> </table> | Baseline: | Meditation | Hypnosis | Control | HRSD | 15.87 (7.29) | 12.33 (5.41) | 15.81 (8.01) | <p>Data Used Remission on HDRS HRSD 3 month follow-up HRSD endpoint</p> <p>Data Not Used CDRS-SR - not relevant</p> | <p>Group 1 N= 15 Meditation - Meditation and hatha yoga following Inner Resources (IR) programme (Waelde, 1999) Eight weekly group sessions lasting 2 hours each, one 4 hour retreat and one booster session in week 12</p> <p>Group 2 N= 15 Hypnosis - Group led by psychiatrist or clinical psychologist Ten weekly sessions lasting 1 1/2 hours each and one 2 hour booster session in week 12</p> <p>Group 3 N= 16 Control</p> | Funding: Mental Insight Foundation and the Stanford Centre on Stress and Health |
| Baseline: | Meditation | Hypnosis | Control | | | | | | | | | |
| HRSD | 15.87 (7.29) | 12.33 (5.41) | 15.81 (8.01) | | | | | | | | | |
| DUNN2005 | <p>Study Type: RCT Type of Analysis: ITT; LOCF method. Blindness: Single blind Duration (days): Mean 84 Setting: Mass media; USA Notes: Randomisation was implemented with sequentially numbered, opaque, sealed envelopes. Info on Screening Process: 765 screened. 685 excluded; 430 didn't meet inclusion criteria, 192 refused to participate and 51 excluded for other reasons.</p> <p>n= 80 Age: Mean 36 Range 20-45 Sex: 20 males 60 females</p> <p>Diagnosis: 100% MDD or minor depression or dysthymia by DSM-IV SCID</p> <p>Exclusions: 160% over ideal weight, consumption of over 21 alcoholic drinks per week, attempt of suicide in the last 2 years or at suicidal risk assessed by SCID interview, hospitalisation for a psychiatric disorder in the last 5 years, current participation in other clinical trials, plans to move from the Dallas area in the next 6 months, current substance abuse or recreational drug use ascertained by SCID diagnosis and urinalysis testing, inability to exercise due to a medical condition, or for women, planned pregnancy or current pregnancy.</p> <table border="0"> <tr> <td>Baseline:</td> <td>HRSD (17 item) LD3 = 19.3 (2.6); LD5 = 19.2 (2.3); PHD3 = 19.1 (1.8); PHD5 = 19.1 (2.2); Control = 20.5 (2.4)</td> </tr> </table> | Baseline: | HRSD (17 item) LD3 = 19.3 (2.6); LD5 = 19.2 (2.3); PHD3 = 19.1 (1.8); PHD5 = 19.1 (2.2); Control = 20.5 (2.4) | <p>Data Used BDI</p> | <p>Group 1 N= 16 Physical activity - 3 times a week for 12 weeks - LD3. Weekly energy expenditure; 7kcal/kg/week.</p> <p>Group 2 N= 18 Physical activity - 5 times a week for 12 weeks - LD5. Weekly energy expenditure; 7kcal/kg/week.</p> <p>Group 3 N= 17 Physical activity - 3 times a week for 12 weeks - PHD3. Weekly energy expenditure; 17.5kcal/kg/week.</p> <p>Group 4 N= 16 Physical activity - 5 times a week for 12 weeks - PHD5. Weekly energy expenditure; 17.5kcal/kg/week.</p> <p>Group 5 N= 13 Control - 3 times a week for 12 weeks - 3 days a week of stretching flexibility exercise for 15-20 minutes per session.</p> | SIGN 1+; funded in part by NIMH 57031 and Technogym. | | | | | | |
| Baseline: | HRSD (17 item) LD3 = 19.3 (2.6); LD5 = 19.2 (2.3); PHD3 = 19.1 (1.8); PHD5 = 19.1 (2.2); Control = 20.5 (2.4) | | | | | | | | | | | |

Results from this paper:

| | LD3 (N=16) | LD5 (N=18) | PHD3 (N=17) | PHD5 (N=16) | Control (N=13) |
|------|------------|------------|-------------|-------------|----------------|
| HRSD | 11.7 (5.8) | 12.8 (5.0) | 9.0 (3.6) | 10.0 (5.5) | 14.0 (4.9) |
| Rem. | 4 (25%) | 2 (11%) | 7 (41%) | 5 (31%) | 2 (15%) |
| Res. | 6 (38%) | 1 (6%) | 7 (41%) | 7 (44%) | 3 (23%) |

HABOUSH2006

Study Type: RCT

Type of Analysis: Completers

n= 20

Age: Mean 69

Sex: 7 males 13 females

Data Used

Beck Hopelessness scale

SCL-90-R (global symptoms)

Geriatric depression scale

Group 1 N= 12

Physical activity - Once per week for 8 weeks - 8 private ballroom dancing

lessons based on 6 dances (foxtrot, waltz,

SIGN 1+; details of funding not stated.²⁷

| <p>Blindness: Single blind Duration (days): Mean 56 Followup: 3 months (84 days) Setting: Newspaper advertisements, information flyers and presentations; USA Notes: No details of randomisation. Info on Screening Process: No data on no. of participants screened. 25 participants recruited.</p> | <p>Diagnosis: 100% No formal diagnosis</p> <p>Exclusions: Younger than 60 years of age, presence of terminal illnesses, presence of physical handicaps that would make dancing difficult, concurrent psychological or psychiatric treatment, presence of self-reported or evident thought disorders, bipolar disorder, alcoholism/substance dependence, or immediate suicide risk, a score of lower than 10 on the HRSD, and presence of apparent cognitive impairment as evidenced by a score of lower than 8 on the MSQ.</p> <p>Notes: Score of 10 or above on the HRSD used to diagnose depression. Also used the Geriatric Depression Scale and SCL-90R.</p> <p>Baseline: Exercise Wait-List HRSD 17.33 (4.27) 18.92 (5.01)</p> | <p>HRSD</p> <p>Notes: Also used the Therapeutic Reactance Scale and a self-efficacy measure.</p> | <p>rumba, cha-cha, swing, and tango). 45 minutes each.</p> <p>Group 2 N= 12</p> <p>Wait list - Group was told that their ballroom dancing lessons were delayed by 8 weeks.</p> | | | | | | | | | | | | | | | | |
|---|---|--|--|--|--|----------|-----------|-------------|--|--|---------|--------------|--------------|-------------|--|--|----------|-------------|--------------|
| <p>Results from this paper:</p> <table> <thead> <tr> <th></th> <th>Exercise</th> <th>Wait-List</th> </tr> </thead> <tbody> <tr> <td>HRSD</td> <td></td> <td></td> </tr> <tr> <td>8 weeks</td> <td>12.80 (5.69)</td> <td>16.00 (6.67)</td> </tr> <tr> <td>HRSD</td> <td></td> <td></td> </tr> <tr> <td>12 weeks</td> <td>8.90 (6.61)</td> <td>11.00 (5.15)</td> </tr> </tbody> </table> | | | | | | Exercise | Wait-List | HRSD | | | 8 weeks | 12.80 (5.69) | 16.00 (6.67) | HRSD | | | 12 weeks | 8.90 (6.61) | 11.00 (5.15) |
| | Exercise | Wait-List | | | | | | | | | | | | | | | | | |
| HRSD | | | | | | | | | | | | | | | | | | | |
| 8 weeks | 12.80 (5.69) | 16.00 (6.67) | | | | | | | | | | | | | | | | | |
| HRSD | | | | | | | | | | | | | | | | | | | |
| 12 weeks | 8.90 (6.61) | 11.00 (5.15) | | | | | | | | | | | | | | | | | |
| <p>HOFFMAN2008</p> <p>Study Type: RCT</p> <p>Type of Analysis: ITT: LOCF</p> <p>Blindness: Double blind in case of drug/placebo</p> <p>Duration (days): Mean 112</p> <p>Notes: RANDOMISATION: no details</p> | <p>n= 202</p> <p>Age: Mean 52</p> <p>Sex: 49 males 153 females</p> <p>Diagnosis: 100% Major depression by DSM-IV</p> <p>Exclusions: Presence of another primary psychiatric diagnosis, under 40 years of age, currently involved in regular exercise, currently involved in psychiatric treatment, medical comorbidities, current use of antidepressants or other psychotropic medications, dietary supplements or herbal therapies with purported psychoactive indications, current active alcohol or drug abuse or dependence, or active suicidal intent.</p> <p>Baseline: HAMD: Supervised = 16.4 (3.7); Home-based = 17.3 (4.6); Sertraline = 16.1 (4.4); Placebo = 17.2 (4.3)</p> | <p>Data Used Remission on HAM-D HAM-D</p> <p>Data Not Used Battery of neurocognitive assessments - not relevant</p> | <p>Group 1 N= 51 Physical activity (supervised) - Three times per week for 16 weeks</p> <p>Group 2 N= 53 Physical activity (non-supervised) - Initial training session with exercise physiologist; exercise programme; two follow-up sessions</p> <p>Group 3 N= 49 Sertraline - Double blind</p> <p>Group 4 N= 49 Placebo - Double blind</p> | <p>Funding: National Institutes of Health grant and General Clinical Research Centre Program grant; medication and placebo pills provided by grant from Pfizer Pharmaceuticals, Inc.</p> | | | | | | | | | | | | | | | |
| KNUBBEN2007 | | | | | | | | | | | | | | | | | | | |

| | | | | |
|--|--|--|--|---|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 10 Range 10-10</p> <p>Setting: Patients admitted to university hospital for treatment of a major depressive episode; Germany</p> <p>Notes: No outcome data provided due to measures used. Participants were taking different antidepressants. Randomisation stratified based on antidepressant.</p> <p>Info on Screening Process: 45 screened. 7 were excluded because they did not meet the inclusion criteria.</p> | <p>n= 38</p> <p>Age: Mean 50</p> <p>Sex: 17 males 21 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 34% Moderate depressive episode by DSM-IV 3% Dysthymia by DSM-IV 42% Intermittent depressive disorder by DSM-IV <p>Exclusions: Score equal to or less than 12 on the Bech-Rafaelsen Melancholy Scale (BRMS), aged below 20 and above 70 years, unable to walk, unable to understand written German, associated organic disease, schizophrenic</p> | <p>Data Used</p> <p>CES-D</p> <p>Notes: Also used BRMS (Bech-Rafaelsen Melancholy Scale).</p> | <p>Group 1 N= 20</p> <p>Physical activity - 30 minutes daily for 10 days - Walking on treadmill daily for 30 minutes. Regimen designed according to an interval-training pattern.</p> <p>Group 2 N= 18</p> <p>Control - 30 minutes daily for 10 days - 30 minutes of light stretching.</p> | <p>SIGN +1; no details of funding stated.</p> |
|--|--|--|--|---|

28

| | <p>Notes: 1 participant was diagnosed with a persistent affective disorder, whilst 7 participants were diagnosed with moderate to severe bipolar disorder.</p> <p>Baseline: Intervention Control</p> <table border="1"> <tr> <td>BRMS</td><td>17.6 (3.7)</td><td>18.7 (4.2)</td></tr> <tr> <td>CES-D</td><td>37.6 (12.9)</td><td>39.2 (8.5)</td></tr> </table> | BRMS | 17.6 (3.7) | 18.7 (4.2) | CES-D | 37.6 (12.9) | 39.2 (8.5) | | | | | | |
|---------------------------------|---|--|------------|-----------------|----------------|----------------|--------------------|--------------------|---|--|-------------|--|--|
| BRMS | 17.6 (3.7) | 18.7 (4.2) | | | | | | | | | | | |
| CES-D | 37.6 (12.9) | 39.2 (8.5) | | | | | | | | | | | |
| Results from this paper: | | | | | | | | | | | | | |
| | <table border="1"> <thead> <tr> <th>Intervention</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>BRMS</td><td>11.2 (4.0)</td></tr> <tr> <td>CES-D</td><td>22.4 (10.)</td></tr> <tr> <td></td><td>15.5 (6.1)</td></tr> <tr> <td></td><td>31.8 (11.2)</td></tr> </tbody> </table> | Intervention | Control | BRMS | 11.2 (4.0) | CES-D | 22.4 (10.) | | 15.5 (6.1) | | 31.8 (11.2) | | |
| Intervention | Control | | | | | | | | | | | | |
| BRMS | 11.2 (4.0) | | | | | | | | | | | | |
| CES-D | 22.4 (10.) | | | | | | | | | | | | |
| | 15.5 (6.1) | | | | | | | | | | | | |
| | 31.8 (11.2) | | | | | | | | | | | | |
| MATHER2002 | <p>Study Type: RCT</p> <p>Type of Analysis: Completers</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 70</p> <p>Followup: 34 weeks (238 days)</p> <p>Setting: Recruited by research nurse over 15 months from primary care; UK</p> <p>Notes: Computer generated randomisation. Used sealed envelopes.</p> <p>Info on Screening Process: 170 people screened. 84 excluded; 7 had no ongoing symptoms, 27 refused to participate, 45 had an absence of depressive symptoms, and 5 had medical contraindications.</p> | <p>n= 86</p> <p>Age: Mean 65 Range 53-91</p> <p>Sex: 27 males 59 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% No formal diagnosis <p>Exclusions: No symptoms of depression, current alcohol or substance misuse, ongoing structured psychotherapy, participation in regular exercise more than twice weekly, specific medical contraindication to exercise, cognitive impairment (<26 on the MMSE), under 53 years of age, and GDS scores of under 10.</p> <p>Notes: All patients had to have been in receipt of a therapeutic dose of antidepressant therapy for at least 6 weeks without evidence of a sustained response prior to study entry.</p> <table border="1"> <thead> <tr> <th>Baseline:</th> <th>Exercise (N=43)</th> <th>Control (N=43)</th> </tr> </thead> <tbody> <tr> <td>HRSD (17 item)</td> <td>16.7 (-2.1 to 3.4)</td> <td>17.4 (-2.1 to 3.4)</td> </tr> </tbody> </table> | Baseline: | Exercise (N=43) | Control (N=43) | HRSD (17 item) | 16.7 (-2.1 to 3.4) | 17.4 (-2.1 to 3.4) | <p>Data Used</p> <p>PGI</p> <p>Geriatric depression scale</p> <p>HRSD</p> <p>Notes: Also used Clinical Global Impression (CGI).</p> <p>Group 1 N= 43</p> <p>Physical activity - Twice a week for 10 weeks - 45 minutes (5-10 minute warm-up period at start and a cool-down period at the end of each session). Predominantly weight-bearing exercise performed to music led by an instructress.</p> <p>Group 2 N= 43</p> <p>Control - Twice a week for 10 weeks - Health education talks at Ninewells Hospital and Medical School, Dundee. Talks lasted for 30-40 minutes and were delivered by medical and nursing staff and staff from professions allied to medicine.</p> <p>SIGN 1+: funded by the Biomedical and Therapeutics Committee of the Chief Scientist's Office, Department of Health.</p> | | | | |
| Baseline: | Exercise (N=43) | Control (N=43) | | | | | | | | | | | |
| HRSD (17 item) | 16.7 (-2.1 to 3.4) | 17.4 (-2.1 to 3.4) | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | |
|---|---|------------------------------------|--|---|----------------|--------------|--|----|--------------|--|--|--|--------------|-------------|--------------|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: Not known</p> <p>Blindness: No mention</p> <p>Duration (days): Mean 21</p> <p>Followup: 12 weeks</p> <p>Setting: Acute care psychiatric treatment facility; USA/Canada?</p> <p>Notes: No details about randomisation. May need to exclude due to N.</p> <p>Info on Screening Process: Doesn't mention.</p> | <p>n= 21</p> <p>Age: Mean 35 Range 19-60</p> <p>Sex: 7 males 14 females</p> <p>Diagnosis:</p> <p>100% Dysthymia</p> <p>Exclusions: History of drug abuse, history of eating disorders, history of psychotic episodes, and not physically capable of performing aerobic and resistance exercises.</p> <p>Notes: No details given of how they were diagnosed.</p> <p>Baseline: Aerobic (N=11) Combined (N=10)</p> <p>BDI 31.00 (9.03) 34.00 (10.79)</p> | <p>Data Used</p> <p>BDI</p> | <p>Group 1 N= 10</p> <p>Physical activity - 3 times a week for 3 weeks - Exercised at 60-70% of target heart rate for 15 minutes on treadmill or stationary exercise bike. Also engaged in resistance exercise using free weights or exercise machines for 30 minutes. 10 min warm-up and 5 min cool.</p> <p>Group 2 N= 11</p> <p>Physical activity - 3 times a week for 3 weeks - Aerobic. Using a treadmill or stationary exercise bike for 45 minutes (including 10 minute warm-up period and 5 minute cool-down). Exercised at or near 60-70% of the participant's target heart rate for 30 minutes.</p> | <p>SIGN 1-; funding details not stated.</p> | | | | | | | | | | | | |
| <p>Results from this paper:</p> <table style="width: 100%; text-align: center;"> <tr> <td>Aerobic (N=11)</td> <td>Comb. (N=10)</td> <td style="width: 20px;"></td> <td style="width: 20px;">29</td> </tr> <tr> <td>BDI(21 item)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>at discharge</td> <td>7.82 (3.22)</td> <td>10.80 (4.78)</td> <td></td> </tr> </table> | | | | | Aerobic (N=11) | Comb. (N=10) | | 29 | BDI(21 item) | | | | at discharge | 7.82 (3.22) | 10.80 (4.78) | |
| Aerobic (N=11) | Comb. (N=10) | | 29 | | | | | | | | | | | | | |
| BDI(21 item) | | | | | | | | | | | | | | | | |
| at discharge | 7.82 (3.22) | 10.80 (4.78) | | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | | | | |
|--|---|---|--|--|------------|---------------|--------------|--|--|-------------|---------------|--------------|--|--|----------|-----------|---------|--|--|
| <table border="1"> <tr> <td>at 6 weeks</td><td>12.82 (12.50)</td><td>11.50 (7.95)</td><td></td><td></td></tr> <tr> <td>at 12 weeks</td><td>17.09 (14.15)</td><td>12.90 (9.59)</td><td></td><td></td></tr> <tr> <td>Rem. (N)</td><td>11 (100%)</td><td>8 (80%)</td><td></td><td></td></tr> </table> | | | | | at 6 weeks | 12.82 (12.50) | 11.50 (7.95) | | | at 12 weeks | 17.09 (14.15) | 12.90 (9.59) | | | Rem. (N) | 11 (100%) | 8 (80%) | | |
| at 6 weeks | 12.82 (12.50) | 11.50 (7.95) | | | | | | | | | | | | | | | | | |
| at 12 weeks | 17.09 (14.15) | 12.90 (9.59) | | | | | | | | | | | | | | | | | |
| Rem. (N) | 11 (100%) | 8 (80%) | | | | | | | | | | | | | | | | | |
| PILU2007 | | | | | | | | | | | | | | | | | | | |
| Study Type: RCT | n= 30 | Data Used | Group 1 N= 10 | SIGN 1-; no funding details given. | | | | | | | | | | | | | | | |
| Type of Analysis: Completers | Age: Range 40-60 | HAM-D | Pharmacological therapy + physical activity - Twice a week for 56 weeks - No details given. | | | | | | | | | | | | | | | | |
| Blindness: No mention | Sex: 100 females | Notes: Also used CGI and GAF (not GAF-self). | | | | | | | | | | | | | | | | | |
| Duration (days): Mean 224 | Diagnosis: | | Group 2 N= 20 | | | | | | | | | | | | | | | | |
| Setting: Clinical registries of psychiatric unit; Italy | 100% MDD or minor depression or dysthymia by DSM-IV SCID | | Control - Twice a week for 56 weeks - 60 minutes. Led by skilled instructor. 5 min warm-up, 50 min physiological strengthening (cardio-fitness machines), and 5 min cool-down. | | | | | | | | | | | | | | | | |
| Notes: Randomised after stratification for comorbidity with anxiety disorders. 13 participants had anxiety disorders also. | Exclusions: Male gender, aged under 40 or above 60 years, responsiveness to at least 1 antidepressant at adequate doses, diagnosis of psychotic disorders, comorbidity with psychiatric disorders other than generalised anxiety disorder, social phobia, panic disorder with or without agoraphobia, any contraindications to physical activity, and diagnosis of neurological and orthopaedic disorders at time of study. | | | | | | | | | | | | | | | | | | |
| Info on Screening Process: 42 were eligible. 12 excluded; refused to participate. | Notes: Specifically treatment resistant MDD. | | | | | | | | | | | | | | | | | | |
| | Baseline: Cases Controls HAM-D 20.5 (7.1) 19.3 (5.7) | | | | | | | | | | | | | | | | | | |
| Results from this paper: | | | | | | | | | | | | | | | | | | | |
| Cases (N=10) | Controls (N=20) | | | | | | | | | | | | | | | | | | |
| HAM-D 8.1 (5.2) | 16.7 (9.1) | | | | | | | | | | | | | | | | | | |
| SIMS2006 | | | | | | | | | | | | | | | | | | | |
| Study Type: RCT | n= 38 | Data Used | Group 1 N= 14 | SIGN 1-; funded by beyondblue (national Depression initiative), the Victorian Centre for Excellence in Depression and Related Disorders. | | | | | | | | | | | | | | | |
| Type of Analysis: ITT | Age: Mean 74 | CES-D | Physical activity - 3 times a week for 10 weeks - Progressive resistance training. 3 sets of 8/10 repetitions at a resistance of 80% of one repetition maximum strengthening exercises using weights for the major upper and lower limb muscle groups. Increased as tolerated. | | | | | | | | | | | | | | | | |
| Blindness: Open | Sex: 17 males 21 females | Geriatric depression scale | | | | | | | | | | | | | | | | | |
| Duration (days): Mean 70 | Diagnosis: | Notes: HAP, PGMS, WHOQOL-BREF, PASE and Self Efficacy and the Decisional Balance Scale also used. | | | | | | | | | | | | | | | | | |
| Followup: 6 months (168 days) | 100% No formal diagnosis | | Group 2 N= 18 | | | | | | | | | | | | | | | | |
| Setting: Recruited via general practices; Australia | Exclusions: Under 65 years of age, unsuitable to exercise (as assessed by PARQ score), alcohol or drug related depression, depression with psychotic features, schizophrenia, bipolar disorder, other psychiatric diagnoses, suicidal ideation, dementia, terminally ill, uncontrolled hypertension, unstable insulin dependent diabetes, unstable angina and those currently receiving antidepressants. | | Control - Advice group. No details given. | | | | | | | | | | | | | | | | |
| Notes: Self-assessed. Randomisation conducted centrally by independent person who ascertained person's allocation from previously block randomised list. | Notes: Depressive symptoms measured using the GDS. | | | | | | | | | | | | | | | | | | |
| Info on Screening Process: 73 people screened. 35 excluded; 14 on antidepressants, 10 medically ineligible and 11 couldn't participate for other reasons. | Baseline: Intervention Control GDS 12.6 (3.6) 12.2 (3.5) CES-D 19.7 (6.4) 16.6 (6.2) | | | | | | | | | | | | | | | | | | |

Results from this paper:

| Intervention | Control |
|------------------|------------|
| GDS 12.2 (5.2) | 12.0 (4.3) |
| CES-D 18.3 (7.5) | 15.3 (6.5) |

| SINGH1997A | | | | |
|---|--|----------------------------|---|---|
| Study Type: RCT | n= 32 | Data Used | Group 1 N= 15 | SIGN 1+; funded in part by |
| Type of Analysis: Completers | Age: Mean 71 | HRSD | Physical activity - 3 times a week for 10 weeks - High progressive resistance training. Supervised, 1 hour followed by 5 minutes of stretching. | the United States |
| Blindness: Single blind | Sex: 15 males 17 females | Geriatric depression scale | | Department of Agriculture |
| Duration (days): Mean 70 | Diagnosis: | BDI | | and Agricultural Research |
| Setting: Recruited from the community through | 53% MDD or minor depression or dysthymia by DSM-IV | | | Service, the Claude Pepper ³⁰ Older Americans Independence Center, and |

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| two volunteer databases; USA. Notes: Only include data for those participants who had sleep outcomes assessed. Of 32 participants, 28 participants' data is analysed. Info on Screening Process: No details. | 41% Unipolar depression by DSM-IV 6% Dysthymia by DSM-IV Exclusions: Under 60 years of age, demented clinically by DSM-IV criteria, score <23 on the Folstein MMSE, suffering with unstable ischemic heart disease or recent myocardial infarction (<6 months), severe progressive neurological disease, symptomatic inguinal hernia, bipolar disorder, active psychosis, suicidal plans, seeing a psychiatrist, participating in progressive resistance training or on antidepressant drugs. Baseline: Weight Training (N=15) Controls (N=13) BDI 21.6 (1.9) 17.0 (1.5) HRSD (17 item) 12.1 (0.9) 11.3 (1.4) | Notes: Also used Pittsburgh Sleep Quality Index (PSQI), and Likert Scales of quality and quantity of Sleep. | Group 2 N= 13 Control - 2 days a week for 10 weeks - Supervised health education programme: 60 minutes. Interactive form of lectures and videos followed by discussion with participation encouraged. Topics were tailored to participants' requests. | the National Institute of Aging. |
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| Results from this paper: | Weight Training (N=15) Controls (N=13) | | | |
| BDI 10.8 (2.6) HRSD (17 item) 5.8 (1.4) | 11.8 (1.8) 8.1 (1.3) | | | |

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|--|--|-------------------|--|---|
| SINGH2005D Study Type: RCT Type of Analysis: Completers Blindness: Single blind Duration (days): Mean 56 Setting: Recruited through 42 individual GPs; Sydney, Australia. Notes: Randomisation by computer generated random number permutation programme in blocks of 15. Info on Screening Process: 451 screened. 391 excluded; not eligible or not interested. | n= 60 Age: Mean 69 Sex: 27 males 33 females Diagnosis: 18% MDD or minor depression or dysthymia by DSM-IV 77% Major depression by DSM-IV 5% Dysthymia by DSM-IV Exclusions: Under 60 years of age, had a GDS score under 14, clinically demented according to DSM-IV criteria, scored under 23 on the Folstein MMSE, suffering from unstable medical disease which would preclude resistance training, had bipolar disorder or active psychosis, were suicidal, currently seeing a psychiatrist, prescribed antidepressant drugs within the last 3 months, or currently participating in any exercise training more than twice a week. Baseline: High Intensity Low Intensity Control HRSD 18.0 (4.5) 19.5 (5.3) 19.7 (3.9) | Data Used HRSD | Group 1 N= 20 Physical activity - 3 times a week for 8 weeks - High intensity weight training. Supervised high intensity PRT of the large muscle groups. Group resistance set at 80% of the one repetition maximum. 60 minutes followed by 5 minutes stretching. Group 2 N= 20 Physical activity - 3 times a week for 8 weeks - Low intensity weight training. Same regimen as high intensity but trained at 20% of the one repetition maximum and didn't progress. 60 minutes followed by 5 minutes of stretching. Group 3 N= 20 Control - Standard care from their GP. | SIGN 1+; details of funding not stated. |
|--|--|-------------------|--|---|

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|--------------------------|---|------------|--|--|
| Results from this paper: | High Intensity (N=18) Low Intensity (N=17) Control (N=19) | | | |
| HRSD (17 item) 8.5 (5.5) | 12.4 (6.3) | 14.4 (6.0) | | |

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|------------------|--|--|--|--|
| TSANG2006 | | | | |
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|-----------------------------|--------------|---|---|---|
| Study Type: RCT | n= 82 | Data Used Geriatric depression scale | Group 1 N= 48 Physical activity - 3 times a week for 16 weeks - Practised Baduanjin under the supervision of a trained qigong practitioner. Each session lasted 30-45 minutes. Asked to practice on their own daily for 15 minutes. | SIGN 1-; funded by Area of Strategic Development Grant A102 of the Department of Rehabilitation Services, The Hong Kong Polytechnic University. |
| Type of Analysis: Not known | Age: Mean 82 | | | 31 |

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| | <p>2% Dysthymia</p> <p>Exclusions: Below 65 years of age, change of medication or its dosage within 4 weeks prior to intervention and throughout intervention period of the study, or cognitive and language impairments.</p> <p>Baseline: Intervention Control GDS 5.17 (2.8) 6.5 (1.4)</p> | <p>Notes: Also used Personal Well Being Index, General Health Questionnaire-12, Self-Concept Scale, Chinese General Self-Efficacy Scale and Perceived Benefit Questionnaire.</p> | <p>Group 2 N=34</p> <p>Control - 3 times a week for 16 weeks - Newspaper reading group was run by a qualified therapist. 30-45 minutes</p> | |
| Results from this paper: | | | | |
| | Intervention Control GDS 3.2 (2.1) 6.2 (1.5) | | | |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|-------------------|---|
| AHMADI2002 | Cohort study (60 experienced body builders before and after exercising, 100 women new to body building vs. 100 experienced body builders, 40 women who had swum for less than 1 month vs. professional swimmers, looked at BDI scores). |
| BARTHOLOMEW2005 | Only 1 hour long. |
| BODIN2004 | Sample size too small (N=12, looked at high and stable self-efficacy exercise vs. low but increasing self efficacy exercise). |
| BONNET2006 | Dissertation synopsis (cognitive therapy alone versus cognitive therapy + exercise combination). Single subject design. |
| CHOU2004 | Total N=14. |
| DAI1999 | Pilot study unrelated to exercise (CBT of minor depressive symptoms in elderly Chinese Americans). |
| DOYNE1987 | Don't provide no. of participants per treatment group. Cannot extract data (aerobic vs. non-aerobic exercise). |
| GUSI2008 | <50% met the criteria for depression. |
| KERR2008 | No relevant comparisons, no relevant outcomes |
| KIM2004 | 75.8% not depressed. Outcome measures used were State Anxiety Inventory (SAI), Depression Status Inventory (DSI) and Self-Esteem Inventory (SER) (meridian exercise vs. control). |
| KRISHNAMURTHY2007 | No formal diagnosis. |
| LEGRAND2007 | N too small (low frequency exercise vs. high frequency exercise vs. group based intervention with high frequency exercise). |
| LENZE2002 | Used SAS as outcome measure. Only used randomised participants who had completed one year of therapy. Not exercise (nortriptyline + IPT vs. nortriptyline + clinic visits vs. placebo + psychotherapy vs. placebo + clinic visits). |
| LEPPAMAKI2002A | Not depressed. |
| MOTL2005 | No formal diagnosis (walking vs. low intensity resistance/flexibility training). |
| NORTH1990 | Review not RCT. |
| PENNINX2002 | Not depressed. |
| SHERWOOD2008 | No relevant outcomes, no relevant comparisons. |
| SINGH2001 | No N per intervention |

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33

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34

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Cognitive behavioural therapies - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes |
|---------------------|--|--|---|--|--|
| Beach1992 (US) | Allocation: random (no details). Duration: 15 weeks; 15-20 sessions | Couples with marital difficulties recruited via press advertisements N = 45 couples Diagnosis: women only - DSM-III for major depression or dysthymia | 1. Cognitive therapy (CT) for female partner - following Beck et al (1979) 2. Behavioural marital therapy (BMT) 3. Waiting list - treatment on demand (3 hours' crisis intervention if required) - no couples requested this | BDI mean endpoint scores | CT and BMT - four therapists - were doctoral level psychologists and 2 advanced graduate students in clinical psychology. All had at least 4 years' full-time graduate training in clinical psychology. Also had 30 hours in each of the 2 treatments by nationally recognised experts before start of study. In Gloaguen. |
| Beutler1991 (US) | Allocation: random (no details). Duration: 20 weeks; 3-month follow-up | Outpatients, moderately depressed, recruited via press, word of mouth and professional recommendation. N=71, mean age = 46.76 years. Diagnosis: DSM-III depression | 1. Group CBT - following Yost et al (1986) and Beck et al (1979) 2. Focused expressive psychotherapy - a Gestalt-based group psychotherapy supplemented by homework assignments 3. Supportive self-directed therapy - weekly telephone contacts of 30 minutes each and reading prescribed books (data not extracted) Group size - 5 - 10 members | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. HRSD mean scores at 3-month follow-up 4. BDI mean scores at 3-month follow-up | Therapists were 4 experienced psychologists trained in CT and focused expressive psychotherapy. Five advanced graduate students conducted supportive self-directed therapy. In Gloaguen. |

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|------------------------|--|---|---|--|---|
| Blackburn 1981 (UK) | Allocation: random (no details). Duration: 20 weeks CT - twice a week for 3 weeks, then once a week. Follow-up study (Blackburn 1986) Duration: 24 months - 6-month continuation treatment (6-weekly appointments), 18 months' naturalistic follow-up | Hospital outpatients (n=49) and GP patients (n=39). Diagnosis: RDC for major depression, BDI ≥ 14 . Follow-up: responders (50% increase in BDI scores) to Blackburn 1981. N = 41, 32 female, mean age 39.2 (+12.2) to 47.9 (+10.0) (reported by group) | 1. CT - following Beck et al (1979) 2. ADs (mixed: GPs and psychiatrists discussed range of ADs and dosages to be offered) 3. 1 + 2 Follow-up: 1. CT - 'booster' sessions every 6 weeks 2. AD - maintained on same drug as in original study 3. 1 and 2 | 1. Leaving the study early 2. Non-responders (<50% decrease in BDI) 3. Relapse (BDI > 9 and HRSD > 8) at 6, 12, 18 and 24 months 4. HRSD mean scores after 6 months' maintenance 5. BDI mean scores after 6 months' maintenance | CT therapists - 2 of the authors AD - GPs and psychiatrists. In Gloaguen. |
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36

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| Blackburn 1997 (UK) | Allocation: random (according to stratified model (endogenous/non-endogenous, gender, age, number of episodes, severity). Evaluators blind to treatment allocation. Duration: 16 week acute phase, 24 month continuation phase. CT - once per week during acute phase, maintenance phase - 3 times in first month, twice in second, monthly thereafter. AD - seen as outpatients roughly every 3 weeks for 30 minutes. | Outpatient referrals to consultants and from 2 general practices. N = 75*, 48 women, mean age between 37.8-40.1 (reported by treatment group) Diagnosis: RDC primary major unipolar depression, HRSD >= 16, current episode was at least 2nd major episode *Total number in study, but only 2 of 3 treatment groups used (n=53). | Acute phase and maintenance phase treatments: 1. AD to AD - consultant or GP free to prescribe any AD provided equivalent to 100mg daily of amitriptyline for TCAs, 45 mg daily of phenelzine for MAOIs, or 20 mg daily of fluoxetine for SSRIs. During maintenance phase, had to be at least at recognised maintenance dose 2. CT to CT - no details 3. AD to CT - as above, but not clear if started CT at 'maintenance dose' (data not extracted for this comparison) | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Non-remitters (HRSD -17>6 or HRSD -24 >8 at endpoint) 4. Leaving the study early 5. HRSD mean scores at 12 and 24 month follow-up 6. BDI mean scores at 12 and 24 month follow-up | Authors acted as CT therapists and had been 'extensively trained' |
| Bright1999 (US) | Allocation: random (blocked for gender and BDI, and then randomly assigned). Duration: 10 weeks, weekly 90-minute sessions | Outpatients recruited via the press N = 98, 70 female, mean age 45.8. Diagnosis: DSM-IIIR for major depression, dysthymia or depression not otherwise specified, HSRD>=10 | 1. Group CBT following Burns (1989) 2. Mutual support group therapy - focused on goals, like interpersonal insight, acquisition of disclosure skills, sharing of advice and feedback Group size - 7 members | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early 4. BDI > 9 5. HRSD > 11 | Therapists were 8 professionals and 6 paraprofessionals (data not extracted for paraprofessionals) |
| Covi1987 (US) | Allocation: random (no details) Duration: 14 weeks, 15 2-hour group sessions | Responders to press ads. N = 70 +90 dropouts, 42 (out of 70) female, mean age (of 70 subjects) 43.8 Diagnosis: RDC diagnosis of major depression of at least 1-month duration, BDI >= 20, HRSD >= 14. | 1. Group CBT: followed Beck et al (1979) and Covi et al (1982). Prior to group, 2 1-hour individual CBT sessions were conducted and a third after first two group sessions. At end of 14 weeks, non-improved patients received 4 additional individual CBT sessions 2. Group CBT + imipramine 3. Traditional group psychotherapy: Based on interpersonal psychodynamic theories Group size: 6-8 members | 1. BDI > 9 2. Leaving the study early | Therapists were a psychiatrist and psychologist who had received 2 years training in CBT. Each therapist served as either main or co- therapist |

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| Elkin1989 (US) | Allocation: random (no details) Duration: 16 weeks - CBT 12 sessions in 1st 8 weeks, then 8 | Outpatients. N = 239, age 21-60 years. Diagnosis: RDC criteria for definite major depression, | 1. CBT - following Beck et al (1979) 2. IPT - aims to help patients achieve a better understanding of their | 1. BDI mean endpoint scores 2. HRSD mean | Therapists were different group of experienced therapists for each condition, |
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| | sessions once a week (20 sessions in total), IPT - 16 weekly sessions with optional 4 additional sessions at therapist discretion (all psychotherapy sessions 50 minutes); imipramine-CM and P-CM groups 16 weekly sessions with one or two additional tapering-off sessions, initial pharmacotherapy session 45-60 minutes, remaining sessions 20-30 mins. | HRSD \geq 14 Early onset group defined as an episode of major depression beginning before age 21 and lasting > 2 years. | interpersonal problems and to improve social functioning. 3. Imipramine-CM - flexible dosage schedule with general goal of achieving 200mg/day by 3rd week, may be increased to 300mg/day. Administered within context of clinical management sessions, to provide supportive atmosphere and for psychiatrist to assess clinical status 4. P-CM - as 3 but with pill placebo | endpoint scores .3 Leaving the study early 4. Non-remitters (HRSD $-17>6$ at endpoint) 5. BDI > 9 at endpoint | except for CM groups which were carried out double blind by same therapists. 28 therapists (10 psychologists, 18 psychiatrists) all trained in pilot stage of project |
| Fava1994 (Italy) | Allocation: random (no details) Duration: 10 40-minute sessions every other week, plus follow-up at 2, 4 and 6 years | Outpatients. N = 43, 26 female, mean age 43.7. Diagnosis: residual symptoms following major depression according to RDC with no evidence of depressed mood after successful treatment of between 3 and 5 months on ADs | 1. CT - following Beck et al (1979) 2. Clinical management - monitoring medication tapering, reviewing clinical status, providing support and advice | 1. Relapse rates at follow-up | Same psychiatrist who was also experienced therapist saw all patients. Integrity of treatment checked by random audio taping of 4 sessions in each group. Relapse = occurrence of RCD-defined episode of major depression |
| Freeman 2002 (UK) | Allocation: random (no details) Duration: 16 sessions | Primary care. Diagnosis: major depression or depression with comorbid anxiety. N = 100, mean age 36 (+-11.2), 79 women | 1. IPT (no details) 2. CBT (no details) 3. TAU (no details) (1 vs 2 extracted for this review; 1 vs 3 in IPT review) | 1. HRSD mean scores at endpoint and 5-month follow-up 2. BDI mean scores at endpoint and 5-month follow-up 3. Leaving the study early | 19 therapists (12 CBT and 7 IPT - none did both), 4 clinical psychologists, 5 research psychologists, 3 psychiatrists, 2 nurse therapists, 1 OT, 4 CPNs. Data sub-set of larger study including wider range of depressive and anxiety disorders. |

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| Gallagher 1982 (US) | Allocation: random (no details, but stratified by age and severity of current episode) Duration: 12 weeks, 16 sessions in all. | Outpatients, referred from regional health centres and private physicians, or self-referred. N = 30 + replacements for dropouts (see Outcomes) 23 female, mean age reported by group: CT 68.3 (+7.7), BT 66 (+5.7), Brief Relational 69 (+4.8) Diagnosis: RDC diagnosis of current definite episode or non- | 1. CT - following Beck et al (1979) 2. BT - following Lewinsohn 3. Brief relational/insight psychotherapy (data not extracted) | 1. Leaving the study early | 4 therapists used in CT and brief relational and 5 in BT. Most advanced PhD candidates in clinical psychology or post-doctoral clinical fellows All had training for therapy which they administered and were supervised by experts. |
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| | | psychotic major depression, BDI > 17 and HRSD > 14 | | | |
| Gallagher-Th94 (US) | Allocation: random (no details) Duration: 16-20 sessions, twice a week for first 4 weeks, then once week for remainder of therapy (c20 weeks) | Outpatients - caregivers recruited through referrals from healthcare professionals approached by letter. N = 66, 61 female, mean age 62 (+9.7) Diagnosis: RDC definite or probable major depression (n=45), RDC minor depression (n=20) or intermittent depressive disorder (n=1) (mean baseline BDI 19.2) Cared for elderly relatives. | 1. CT following Beck et al (1979) and Lewinsohn et al (1985) 2. Brief psychodynamic therapy (Mann, 1973) | 1. Still meeting RDC criteria for major/minor/intermittent depression) at endpoint and 3-month follow-up 2. Leaving the study early | 13 therapists, each saw at least one client. Four were skilled in both therapies, so treated clients in both conditions. 2 had terminal master's degrees in social work, rest were PhD-level psychologists. All had at least 1 year of supervised experience doing psychotherapy with depressed elderly people. |
| Hautzinger (in-pats) | See Hautzinger 1996 This is data from inpatients - data for both groups not reported together | | | | |
| Hautzinger 1996 (Ge) | Allocation: random (no details, but done independently of researchers). Duration: 8 weeks + 1-year follow-up CBT - 24 sessions, 50-60 minutes long. AD - Clinical management for 20 minutes a week | Inpatients (in a psychiatric clinic) and outpatients. N = 191, 120 women, mean age 38.8 (+9.9). Diagnosis: ICD9/DSM-III-R for major depression HRSD \geq 20 BDI \geq 20. 80.4% had major depression (DSM-III-R), 19.6% dysthymia | 1. CBT - following Lewinsohn (1974) and Beck (1974) 2. Amitriptyline - Week 1: 50-100mg/day Weeks 2-7: 150mg/day Week 8: stopped or continued depending on patient status + clinical management 3. 1 and 2 (without clinical management) | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early 4. HRSD mean scores at 12-month follow-up 5. BDI mean scores at 12-month follow-up | Clinical psychologists and psychiatrists with at least 1 year clinical psychiatric experience |
| Jarrett1999 (US) | Allocation: random, blind to research personnel, supervised by statistician, stratified by length of current episode and marital status. Acute phase + continuation phase. Acute phase: duration: 10 weeks. CT = 20 sessions twice weekly Pharmacological | Outpatients, recruited through media, printed announcements, self or practitioner referrals. Acute phase: N = 108, 73 women, mean age 39.6. Diagnosis: DSM-III-R for major depression, HRSD \geq 14, definite atypical depression Continuation phase: responders only, defined as | Acute phase: 1. CT following Beck et al (1979) 2. CM* + phenelzine - gradually increased over 10 weeks to 0.85mg/kg or 1mg/kg in patients not responding to lower dose. 3. CM* + placebo * 2 and 3 - used treatment manual modelled on NIMH Treatment of Depression Collaborative Research Program - sessions involved adjusting medication, recording symptoms, side effects, weight, blood | 1. BDI mean endpoint scores 2. HRSD-21 mean endpoint scores 3. Leaving the study early 4. Relapse at endpoint, 12-month and 24-month follow-up | Therapists - 2 were doctoral-level clinical psychologists, 1 was a psychiatrist. Offsite consultant used Cognitive Therapy Scale to evaluate competence and provide feedback. Therapists participated in weekly group supervision. |

treatments: 11 sessions over 10 weeks

HRSD < = 9, not meeting DSM-II-R for MDD at post-

pressure. Not clear if included same support element as in Elkin1989. When symptom

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| | Continuation phase: 8 months more treatment plus 16-month follow-up. CT - 10 sessions over 8 months. Pharmacotherapy: 10 sessions over 8 months WLC - 10 sessions with evaluator over 8 months | acute phase blind evaluation, completed acute phase treatment. N = 31, 26 female, mean age 41.2 (+10.5) | reduction and monoamine oxidase inhibition of 80% or more were achieved, patient continued to receive that dose. Compliance assessed by pill counts and patient diaries. Continuation phase: 1. Acute phase CT + continuation CT 2. Acute phase CT + no continuation treatment 3. Acute phase phenelzine + continuation phenelzine (maintained on acute phase dose) 4. Acute phase phenelzine + no continuation treatment 5. Acute phase placebo + continuation placebo 6. Acute phase placebo + no continuation treatment | | |
| Jarrett2001 (US) | Allocation: random, using statistical software, double blind. Duration: 20 sessions over 12-14 weeks | Outpatients recruited through media, announcements and referrals. N=84, 61 female, mean age 42.74 (+1.14). Diagnosis: responders (no MDD, HRSD <= 9) to acute phase where were diagnosed according to DSM-IV. | 1. CBT - following Jarrett unpublished manual designed to teach responders to prevent relapse 2. Evaluation only | 1. Leaving the study early | 5 experienced therapists provided CBT. Each had at least 1 year of training. Competence evaluated by off-site consultant. Therapists received weekly supervision. |
| Keller2000 (US) | Allocation: random, central computerised randomisation schedule. Assessors blind to treatment group. Duration: 12 weeks. Therapy group - twice-weekly sessions in weeks 1 to 4 (could be extended to week 8 if necessary), weekly weeks 5 to 12. AD group - 15-20 minutes per visit. Psychopharmacologists | Outpatients recruited from 12 academic centres. N = 681, 65.3% female, mean age 43 (+10.7) Diagnosis: DSM-IV for chronic major depressive disorder, current major depressive disorder superimposed on pre-existing dysthymic disorder, recurrent major depressive disorder with incomplete remission between episodes in a patient with a current | 1. Cognitive behavioural-analysis system of psychotherapy (draws on behavioural, cognitive, and interpersonal techniques of other therapies. Teaches patient to focus on consequences of behaviour and to use social problem-solving algorithm to address interpersonal difficulties. Differs from CBT by focusing primarily on interpersonal interactions.) 2. Nefazodone + CM (following NIMH manual) - initially 200mg/day, then 300 mg/day in 2nd week. Increased weekly in increments of 100mg/day to maximum of | 1. Non-remitters (HRSD -17>6 or HRSD -24 >8) 2. Leaving the study early 3. HRSD-24 mean endpoint scores | Psychotherapists: minimum 2 years' experience after MD or PhD or minimum 5 years' experience after MSW. Also attended 2-day training workshop, with competence being evaluated during pilot cases. Dropout and remission data extracted on full ITT basis. HRSD at end of treatment reported as 'modified ITT' - i.e. only those who received at least one treatment session. |

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| | not allowed to make formal psychotherapeutic interventions HRSD >=20 | major depressive disorder, HRSD-24 >=20. | 600mg/day. To remain in study patients had to be on at least 300mg/day by week 3. 3 1 and 2 | | |
| Klein1984 (US) | Allocation: random (no details). Duration: 12, 2-hour, weekly sessions | Recruited via local newspaper. Diagnosis: Met RDC criteria for major or minor depression, not receiving any other treatment for depression, not displaying psychotic or bipolar disorder or imminent suicide risk. N = 74, 53 female, mean age 30 | 1. Group therapy (CBT/IPT) 2. Group meditation-relaxation therapy 3. Running therapy (not extracted) | 1. Leaving the study early | Dropout rates were the only extractable data. 4 therapists - all conducted running therapy, 2 conducted meditation therapy as well, 1 of those and 1 other conducted group CT. All were mental health professionals. |
| Miller1989 (US) | Allocation: random (no details). Duration: 3 weeks in hospital + 20 weeks post-hospital. Standard treatment: 20-minutes once per day in hospital, 6-8 times during outpatient period. Cognitive therapy: 50 minutes once per day in hospital (from 3rd week), once per week as outpatient. Therapists could increase frequency if required. Social skills training: 50 minutes once per day in hospital (from 3rd week), once per week as outpatient. Therapists could increase frequency if required. | Inpatients - recent admissions to private psychiatric hospital in US. N = 46, 34 female, age 18-65, 30 married. Diagnosis: Major depression according to Diagnostic Interview Schedule BDI > 17 HRSD > 17 History of depression - mean no. of previous episodes 6.7; 44% also had dysthymia | 1. Standard treatment: usual hospital milieu, medication (amitriptyline or desipramine) + other medication as considered appropriate, and management sessions with psychiatrist 2. Cognitive therapy: standard treatment (as above) + CT as per Beck et al manual (1976) 3. Social skills training: based on Bellack et al (1981) and Monti et al (1982) (data not extracted) | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early 4. BDI > 9 at endpoint 5. Non-remitters (HRSD -17>6 or HRSD -24 >8) 6.HRSD > 6 at endpoint | Pharmacotherapy and maintenance conducted by 7 board-certified psychiatrists Cognitive therapy conducted by a PhD clinical psychologist with 6 years' experience of CT with depressed patients. Social skills training administered by post-internship clinical psychology PhD candidate with 12 years' experience, supervised by PhD clinical psychologist with 10 years' experience. |

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| Miranda 2003 (US) | Allocation: random (computer generated); assessors blind to allocation. Duration: 6 months. CT = 8 sessions | Women screened in Women, Infants and Children food su- bsidy programmes targeting low-income pregnant and post-partum women or Title | 1. CBT (8 weekly sessions + 8 more if needed, n=15) - manual-guided treatment adapted from 12-session patient and therapist manuals developed for low- income English and Spanish speaking | 1. Mean HRSD endpoint scores 2. Non-remitters (HRSD> 7) | Medication - treated by primary care nurse practitioners supervised by a board-certified psychiatrist; weekly telephone calls to assess |
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| | (+8 more if needed) | X family planning clinics for young and low-income women; all from 3 cultural groups (Black women born in US n=117, Latinas born in Latin America n=134 and white women born in US n=16). N = 267, all female, mean age 29.3 (+-7.9). Diagnosis: Major depressive disorder (diagnosed by telephone interview) | medication patients. Shortened to 8 sessions by including more topics per session and modified to be more sensitive to the issues of young women and those with histories of interpersonal trauma. Therapists also trained in PTSD and trauma. 2. Medication - paroxetine 10mg-50mg (mean 30 mg) (n=18 switched to bupropion because of side effects) for 6 months 3. Referral to community care - education about mental health treatments available in the community and about depression. Clinician offered to make an appointment for the women at the end of the clinical interview. Referred patients were contacted to encourage them to attend the intake appointment for care. All participants assigned to CBT or antidepressants invited to up to 4 education meetings with clinician overseeing their treatment. | | adverse effects, adherence and treatment effects. CBT - treated by experienced psychotherapists supervised by licensed clinical psychologist with CBT expertise. Bilingual providers treated Spanish-speaking women and all written material was available in Spanish. |
| Murphy 1984 (US) | Allocation: random (according to pre-arranged system based on their unique and permanent clinic registration number). Only principal investigator knew assignment, and had no contact with patients except to draw occasional blood sample. Duration: 12 weeks, plus 1-month follow-up. CT - 50-minute sessions, twice weekly for first 8 weeks, then weekly for final 4 weeks. 1-, 6- and 12-month follow-up. | Outpatients N = 87 (1 treatment group not extracted, therefore n=70). Characteristics available for completers only - 52 female, mean age 33.8 (10.4) Diagnosis: primary, unipolar affective disorder (DSM-III), BDI >= 20, HRSD >=14 | 1. CT - following Beck et al (1979) 2.Nortriptyline hydrochloride (equivalent to 25 mg nortriptyline base) 3. CT + placebo (not extracted) 4. CT and TCA | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Relapse at 6 and 12 months 4. Leaving the study early 5. Non-remitters (HRSD -17>6 or HRSD -24 >8) 6. BDI > 9 at endpoint and 12 months 7. HRSD mean scores at 1 month follow up 8. BDI mean scores at 1 month follow up 9.HRSD > 6 at endpoint | Therapists were 3 psychologists and 9 psychiatrists Pharmacotherapy administered by the psychiatrists. Psychiatrists training ranged from 2nd year residency to post residency. Psychologists had completed doctoral requirements except for dissertation. Therapists received pre-study training. |
| Murphy 1995 (US) | Allocation: random using table of random numbers, | Outpatients recruited via the press N= 37 (1 treatment | 1. CBT - following Beck et al (1979) 2. Relaxation training (not extracted) | 1. BDI > 9 at endpoint | CBT therapists - 3 psychologists with at least 3 |

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| | concealed from patient until after randomisation Duration: 16 weeks. Therapy sessions: 50 minutes, 1 or 2 times a week for first 4 weeks, then once per week, to max of 20. AD group - 20 minutes weekly for 4 weeks, then weekly or bi-weekly as appropriate. | group not extracted, therefore, n=23), 26 female, mean age 39.4 (+10.9) Diagnosis: DSM-III-R for unipolar affective disorder, depressed, BDI >= 14, HRSD > = 10 | 3 Desipramine - 150-300 mg daily | | years' supervised clinical experience, given pre-treatment supervision and training, consisting of weekly supervision over period of several months Relaxation therapists: 3 psychologists and social worker ADs administered by psychiatrist |
| Paykel1999 (UK) | Allocation: random, consecutively numbered sealed envelopes prepared by statistician and stratified by centre, previous major depressive episodes (>=2 or <2), length of present illness (>=1 year and < 1 year), and severity of depression Duration: 16 sessions over 20 weeks, booster sessions 6 and 13 weeks into 1-year follow-up. Drug continuation and clinical management continued for follow-up year | Psychiatric outpatients with residual symptoms; N=158, 78 female, mean age 43.2(+11.2) control group, 43.5(+9.8) CT group. Diagnosis: DSM-III-R for major depression within last 18 months with residual symptoms for at least 8 weeks at randomisation (HRSD >= 8, BDI >=9), and had to have been taking ADs for at least previous 8 weeks, with 4 weeks at equivalent to 125mg amitriptyline. Excluded if had CT of > 5 sessions previously. | 1. Drug continuation and clinical management: 30-minute session every 4 weeks with study psychiatrist for 20 weeks, then every 8 weeks. AD dosage allowed to increase by 30% 2. Drug continuation and clinical management + CT: as above, plus 16 CT sessions over 20 weeks, plus 2 booster sessions at approximately week 26 and 32. Based on Beck et al (1979) with a manual | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early 4. Relapse at endpoint 5. Relapse at follow-up 6. HRSD mean scores at follow-up 7. BDI mean scores at follow-up | CT therapist trained and experienced in CT, regular joint supervision during study by principal author, plus independent rating of audiotapes. |
| Rosner1999 (Ge) | Allocation: random (no details). Duration: 20 weeks, 1 session per week. | Outpatients n = 76 (1 treatment group not extracted, therefore n=43) Diagnosis: DMS-III for major depression HRSD >= 16 | 1. CBT - following Beck et al (1979) 2. Gestalt therapy 3. Bibliotherapy (data not extracted) | 1. BDI mean endpoint scores | Psychologists or psychiatrists with 10 years' experience. |
| Scott1992 (UK) | Allocation: random using pre-prepared sealed envelopes Duration: 16 weeks; CBT | Outpatients referred by 63 GPs in Edinburgh; N = 121 (data for 2 treatment groups not used, therefore n=61), 91 | 1. Usual GP care (19/29 included ADs, but only 14 at dose equivalent to therapeutic dose of amitriptyline) 2. Amitriptyline prescribed by research | 1. HRSD mean endpoint scores 2. Leaving the study early | CBT therapists - research clinical psychologists, trained in Beck et al (1979) techniques. Social work - 2 qualified social |

50-minute sessions,
weekly at start and then

women, mean age between
28.8 (+8.1) and 36.2 (+-14.2)

psychiatrist - 50-75mg daily, gradually
increasing to 150mg daily. Patients seen

workers, with experience of
medical and psychiatric

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| | variable intervals | (reported by treatment group). Diagnosis: DSM-III for major depressive episode | weekly for 2 weeks, then fortnightly/monthly as required. 3. CBT - based on Beck et al 4. Social work - detailed social assessment leading to construction of a problem list and thereafter an intervention programme. Initial sessions weekly but thereafter sessions were flexible. Strategies included support by encouragement and listening, help to understand feelings, practical advice, rehearsing events, support by the exercise of authority, advocacy on patient's behalf, arranging social support or holidays, marital/family meetings if appropriate. | | hospital patients. Assessments by independent trained raters who were initially blind to treatment group, but likely that patients made them aware of allocation at later meetings. |
| Scott1997 (UK) | Allocation: random (no details). Duration: 6 weeks, 30-minute weekly sessions. 12-month follow-up (data not extracted as > 50% dropout/lost to follow-up) | GP referrals N = 48, 32 female, mean age 41(10.4) Diagnosis: DSM-III-R for major depression, BDI>=20 and depressive episode of < 2 years 29 had previous episode | 1. Usual GP care (all but 1 patient in each group prescribed ADs) 2. GP care + brief cognitive therapy - including homework and schema-based therapy. | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early | No therapist details |
| Selmi1990 (US) | Allocation: random (no details). Duration: 6 weeks, 6 sessions | Recruited via the press N = 36, 23 female, mean age 28.2(4.58). Diagnosis: SCL-90-R >= 65th percentile for psychiatric outpatients (on 13-item depression scale), BDI >= 16 and current Research Diagnostic Criteria diagnoses of major/ minor/ intermittent depressive disorder based on modified version of Schedule for Affective Disorders and Schizophrenia | 1. CCBT - written by one of the authors in MIIS-CONVERSE who was trained in CBT (data not extracted) 2. CBT - used treatment manual following same procedures as CCBT 3. Wait list control - participants could call for an appointment if needed, but none did. | 1. BDI mean endpoint scores 2. BDI > 9 at endpoint 3.HRSD > 6 at endpoint | Therapist - advanced graduate student in clinical psychology with same training in CBT as author of computer programme |

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| Shapiro (Mild) | Shapiro 1994. | Mild defined as BDI scores 16-20 | | See Shapiro 1994. | Data from mild, moderate and severe cases reported separately. |
| Shapiro | Shapiro 1994 | Moderate defined as BDI | | See Shapiro 1994. | Data from mild, moderate and |

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| (Mod) | | scores 21-26 | | | severe cases reported separately. |
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| Shapiro 1994 (UK) | Allocation: random (no details). Duration: 8- and 16-week versions of therapies (16-week extracted for main comparisons). 1-hour weekly sessions. Follow-up at 45 weeks after pre-screening - for 16-week therapy, equivalent to 15 weeks after end of treatment. | Outpatients, recruited from self-referrers responding to recommendations by occupational health personnel or responding to publicity materials distributed at the workplace or by GPs, or referred directly by GPs or mental health services. N = 117, 61 female, mean age 40.5 (+-9.5) Diagnosis: DSM-III for MDD | 1. CBT - a multimodal method somewhat more behavioural in emphasis than Beck et al, 1979) 2. Psychodynamic-interpersonal psychotherapy - based on Hobson's conversational model | 1. BDI mean endpoint scores 2.BDI mean scores at 6 and 12 months' follow-up | Five therapists - UK-trained clinical psychologists, 2 had post qualification training in PI methods and trained the others. All had at least 2 training cases in each treatment x duration conditions. Data for 8-week therapy conditions extracted for short term therapy comparison only. 25 participants on medication at beginning of study - not clear if still the case at the end. |
| Teasdale 2000 (UK) | Allocation: random using central independent allocator. Duration: 60 weeks. Individual orientation session plus 8 weekly 2-hour group sessions, plus 52-week follow-up phase. | Outpatients in remission, recruited via community health care facilities and media announcements at 3 sites (2 in the UK: Bangor, and Cambridge; 1 in Canada: Ontario) n = 145, 110 female, mean age TAU group: 46.2 (+-9.6); MBCT group: 40.7 (+-10.3). Diagnosis: DSM-III-R for recurrent major depression, with at least 2 previous episodes in past 5 years, with one in last 2 years. History of treatment with ADs and in recovery/remission. Baseline HRSD < 10. | 1. Treatment as usual (TAU) - participants instructed to seek help from family doctor or other sources as they normally would. 40% of TAU group and 45% of MBCT group on ADs for mean of 32.7 (+-21.2) and 23.3 (+-17.9) weeks respectively. 2. TAU and MBCT - mindfulness-based CBT. Group intervention based on CBT (Beck et al, 1979) with components of MBSR programme developed by Kabat-Zinn (e.g. Kabat-Zinn et al, 1990). Includes with daily homework exercises. | 1. Relapse (or recurrence) meeting DSM-III-R criteria for major depressive episode, assessed by the Structured Clinical Interview for DSM-III-R administered at bi-monthly assessments throughout follow-up. Data extracted is relapse over whole study period. 2. Leaving the study early | Instructors were experienced cognitive therapists who developed the MBCT programme. |

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| Teasdale 2003 (UK) | Allocation: random using central independent allocator. Duration: 60 weeks. Individual orientation session plus 8 weekly 2-hour group | Patients in remission, recruited via GPs and local newspaper advertisements.N = 75, 57 female, mean age TAU group: 46.1 (+-9.3); MBCT group: 42.9 (+-8.4) | 1. Treatment as usual (TAU) - participants instructed to seek help from family doctor or other sources as they normally would. Split by up to 2 episodes/>2 episodes: 36%/33% of TAU group and 13%/21% of MBCT group on ADs for mean of 32.7 (+- | 1. Relapse (or recurrence) meeting DSM-III-R criteria for major depressive episode, assessed by the Structured Clinical | Instructors were experienced cognitive therapists who had led at least 2 groups through the MBCT programme. |
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| | sessions, plus 52-week follow-up phase. | Diagnosis: enhanced DSM-IV for recurrent major depression, with at least 2 previous episodes in past 5 years, with one in last 2 years. History of treatment with ADs and in recovery/remission. Baseline HRSD TAU group: 5.68 (+- 2.97); MBCT group: 5.7 (+- 3.02) | 21.2) and 23.3 (+-17.9) weeks respectively. 2. TAU and MBCT - mindfulness-based CBT Group intervention based on CBT (Beck et al, 1979) with components of MBSR program developed by Kabat-Zinn (eg Kabat-Zinn et al, 1990). Includes with daily homework exercises. | Interview for DSM-IV administered at completion of 8 training sessions and every 3 months afterwards. Data extracted is relapse over whole study period. | |
| Thompson 2001 (US) | Allocation: random (no details) Duration: 3-4 months, 16-20 sessions in all treatment groups. 1st 4 weeks - 2 sessions per week, then 1 session per week. AD group: 30-minute sessions | Outpatients who responded to media advertisements or referred by community physicians, mental health organisations, and social service agencies N = 100, 67 women, mean age: 66.8 (+- 5.9). Diagnosis: major depression according to RDC on initial screening, HRSD >=14, BDI >= 16 | 1. CT - following Beck (1979), with modifications for older patients to facilitate learning - e.g. slower rates of presentation 2. Desipramine - starting at 10mg, increased according to tolerance. Mean stable daily dose 90 +- 63 mg. Plus CM adapted from NIMH-TDCRP manual for older people sessions to support patients 3. 1 + 2 combined - AD and CT sessions usually conducted back-to-back | 1. BDI mean endpoint scores 2. HRSD mean endpoint scores 3. Leaving the study early | AD group: psychiatrists following NIH-TDCRP protocol. CT group: 8 clinical psychologists with at least 1 year's experience with geriatric patients with psychiatric symptoms |
| Ward 2000 (UK) | Allocation: random. Numbered sealed opaque envelopes, blocked and stratified by severity on BDI. Patients with strong preference could choose treatment or be randomised only between treatment groups (i.e. not GP care), but analysis undertaken for preference group, 3-way randomisation and 2-way randomisation separately. Duration: 6-12 weekly 50-minute sessions - no control over when ended | GP referrals N = 464, mean age 34.8 (12.2), 75% female Diagnosis: BDI >=14, 62% depression main diagnosis, others 'no overall psychiatric diagnosis' or 'behavioural difficulties'. | 1. Usual GP care (30% in counselling group, 27% of CBT group on ADs) 2. CBT - complied with manualised problem formulation and staged intervention approach (Greenberger & Padesky, 1995a, 1995b) 3. Non-directive counselling - used non-directive approach outlined in a manual developed by authors based on Rogers. 2 used in review of CBT | 1. BDI mean scores at endpoint and 12 month follow-up 2. Leaving the study early | Published version of HTA by King et al. Counsellors - accredited by BAC CBT therapists were psychologists accredited by BACP and registered with UK Council for Psychotherapy. Several problems with this trial: a) 27% of CBT group were also prescribed ADs by their GP (despite GPs being asked not to) and data not reported separately b) no control over when sessions were finished (minimum of 6, but up to 12 on offer if necessary). BDI etc scores taken at baseline, 4 months and 12 months, but |

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| | | | | | only managed to get date of therapy completion from 87% in CBT group and of these, only 80 had finished at 4 months. No other information reported on when sessions finished (presumably all within 12 months). c) although inclusion criteria included BDI ≥ 14 , only 62% had main diagnosis of depression. |
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Characteristics of excluded studies

| Study | Reason for exclusion |
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| Barkham1996 (UK) | (CBT vs ?IPT) No usable data. |
| Beck1985 (US) | (CBT vs CBT + AD) Included patients with personality disorder. |
| Beutler1987 (US) | Benzodiazepine (BZD) vs placebo (PBO) vs G-CBT + PBO vs G-CBT + BZD) Not an RCT |
| Bolton2001 (Aust) | (CBT vs GP care) No extractable data - reports HADS not BDI or HRSD |
| Bowers1990 (US) | (CBT + AD vs relaxation therapy + AD vs AD) Inadequate randomisation |
| Chaudhry1998 (Pak) | (CBT + AD vs CBT + PBO) Not an RCT |
| Comas-Diaz1981 (US) | (CBT vs WLC) No evidence that depression diagnosis made according to recognised criteria |
| Dunn1979 (Can) | ('CBT' vs AD + support) Not CBT |
| Dunner1996 (US) | (CBT vs AD) All patients were diagnosed with dysthymia. |
| Fava1998B | (CBT vs well-being therapy) Mixture of primary diagnoses, including panic disorder and OCD |
| Fleming1980 (US) | (G-CBT vs G-BT v G-non-directive therapy) Inadequate randomisation |
| Free1991 (Aus) | (G-CBT) Not an RCT |
| Gendron1996 (Can) | (G-CBT vs support group) Patients not specifically depressed |
| Gordon1987 (US) | (G-CBT vs no treatment control) Participants not diagnosed according to recognised criteria. |
| Green1985 (US) | (Structured multimodal group therapy) Not an RCT |
| Hellerstein2001(US) | (CBT +AD vs AD) All patients were diagnosed with dysthymia. |
| Hirschfeld2002 (US) | ('CBT' vs AD) Not CBT and no relevant outcomes |
| Hogg1988 (US) | (G-CBT vs G-IPT) 27% of participants had adjustment disorder |

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| Hollon1992 (US) | (CBT vs AD vs CBT + AD) Randomised, but dropouts replaced |
| Jarrett1998 | (CBT) Not an RCT |

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| Jong-Meyer1996 (Ge) | (CBT + AD vs supportive therapy + AD) Irrelevant comparison in this review |
| Lapointe1980 (US) | (G-CBT vs G-assertive therapy v G-insight therapy) No extractable data |
| Lenz2000 (Austria) | (CBT) Not an RCT |
| Lewinsohn1990 (US) | Adolescents, therefore outside scope |
| Neimeyer1984 | Unpublished, could not get trial report |
| Macaskill1996 (UK) | (AD vs AD + rational emotive therapy) Participants includes those with co-existing psychiatric disorder |
| Manning1994 (Aus) | (G-CBT + AD) Not an RCT. Patients not exclusively depressed |
| Maynard1993 (US) | (G-CBT vs 'support' group v control) Inclusion criteria did not include a formal diagnosis of depression |
| McNamara1986 (US) | (CT vs BT vs CT + BT v counselling) No evidence that depression diagnosis made according to recognised criteria |
| Meresman1995 (US) | (AD vs G-CBT) Not an RCT |
| Miller1999 (US) | Sub-set of participants in Miller1989. Inadequate randomisation. |
| Moore1997 (UK) | (CT vs AD for residual depression) Study arms < 10 each and only study in comparison |
| O'Leary1990 (US) | Means only given in graph, but cannot be accurately read. No standard deviations although could impute these from F ratios. |
| Pace1993 (US) | (CT vs no treatment control) Diagnosis of depression not made according to recognised diagnostic system |
| Peden2000 (US) | (G-CBT vs no treatment control) Patients not exclusively depressed at start of study |
| Persons1999 (US) | (CT vs CT + AD) Not an RCT |
| Reynolds1986 (US) | Adolescents, therefore outside scope |
| Ross1985 (UK) | (CBT vs G-CBT vs WLC/GP care) No usable data. No clear description of treatment. Randomisation procedure not clear |
| Rotzer1985 | Unpublished, could not get trial report |
| Rush1977 (US) | (CBT vs AD) Medication tapered and discontinued in last 2 weeks of study unlike in other studies |
| Rush1981 (US) | (G-CBT vs individual CBT vs individual CBT + AD) Not fully randomised |
| Scogin1987 | Not CBT |
| Shapiro1982 (UK) | (G-CBT vs individual CBT) Most participants had adjustment disorder |
| Shapiro1987 (UK) | (CBT vs relationship-oriented therapy) Not fully randomised; cross-over design |
| Shaw1977 (Can) | (CBT vs WLC) Diagnosis of depression not made according to recognised diagnostic system |
| Steffen1998 (US) | (CBT vs psychodynamic) Data pooled from 2 studies which have not been published. No within-study data presented only between study, therefore cannot use because randomisation not undertaken between studies |
| Steuer1984 | (G-CBT vs G-psychodynamic) Patients not randomised to treatment groups |
| Stravynski 1994 (Ca) | (G-CBT vs G-CBT + AD) Does not give Ns of each treatment group or numbers leaving the study early. Not clear what Ns are for mean HRSD/ BDI scores at each time point. |
| Taylor1977 (Aust) | (CT vs BT vs CBT) Diagnosis of depression not made according to formal criteria |

Teasdale1984 (UK)

(GP care vs CBT) No usable data

Thomas1987(US)

(G-CBT vs G-self-control therapy) Diagnosis of depression not made according to formal criteria

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| Thompson1987 (US) | (CBT vs psychodynamic) Not clear what patient numbers are used in table reporting outcome measures. Dropout data not fully reported |
| Tschuschke2000 | (G-'analytic' vs G-psychodynamic) Not an RCT; irrelevant comparison for this review |
| Warren1988 (US) | (G-CBT vs WLC) Participants not diagnosed with depression according to accepted criteria at start of study |
| Wierbicki1987 (US) | (G-CBT vs individual CBT) Participants have atypical depression. |

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| Wilson1983 (Aust) | (CT vs BT) Randomised, but dropouts replaced |
| Wilson1990 (US) | (G-CBT vs individual supportive therapy) Compares group CBT with individual support therapy - comparison not usable in this review |
| Wollersheim1992 (US) | (G-CBT vs supportive therapy vs bibliotherapy vs WLC) Therapeutic intervention not CBT |
| Zettle1989 (US) | (G-CBT vs partial G-CBT) Participants not diagnosed according to recognised criteria. |
| Zimmer1987 | Unpublished, could not get trial report |

49

Cognitive behavioural therapies - new studies in the guideline update

Comparisons Included in this Clinical Question

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| CBT vs ADs BAGBY2008 | CBT vs ADs vs Placebo DERUBEIS2005 | CBT vs control therapy (quasi-desensitization procedure) MANBER2008 | CBT vs IPT vs Clinical management MARSHALL2008 |
| CBT vs Non-Directive Psychotherapy (IPT) LUTY2007 | CBT vs REBT vs Ads DAVID2008 | Cognitive therapy vs Behaviour Activation vs ADs vs Placebo DIMIDJIAN2006 | Cognitive therapy vs Behavioural Activation component vs Automatic Thoughts condition JACOBSON1996 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|--|--|--|
| BAGBY2008 Study Type: RCT Type of Analysis: Unclear Blindness: No mention Duration (days): Range 112-140 Setting: Participants solicited through advertisements in local media. Notes: Randomisation: No details of procedure. Info on Screening Process: In trial A, n=307 were screened and n=131 were excluded as they did not meet the criteria for entry. N=171 were randomised. In trial B, n=301 were screened, n=141 were excluded as they did not met the criteria for entry. N=160 were randomised. | n= 280 Age: Mean 42 Range 18-70 Sex: 105 males 175 females Diagnosis: 100% Major depression by DSM-IV SCID Exclusions: <18 and >70 years old, less than 8 years of education, non-fluent in English, unable to give informed consent, not meeting DSM-IV criteria for major depressive episode. Further criteria: presence/history of bipolar disorder, psychotic disorders, or substance use disorders, presence of borderline or antisocial personality disorder as assessed by the SCID-II, current treatment with antidepressant medication or previous treatment with ECT, or concurrent active medical illness. Baseline: HDRS: CBT = 18.9 (3.53), ADs = 18.4 (4.01). | Data Used HDRS (17 item) Leaving study early for any reason Notes: HDRS taken at baseline and endpoint. | Group 1 N= 146 CBT - participants received between 16-20 sessions of CBT weekly. Group 2 N= 129 Pharmacological therapy - Antidepressant therapy for 16-20 weeks. Medications were: bupropion, citalopram, fluoxetine, paroxetine, phenelzine and venlafaxine. | Supported by grants from the Ontario Mental Health Foundation, The Canadian Institute of Health Research, and in part by the National Institution Aging/National Institute of Health (US) Intramural Research Program. |
| DAVID2008 Study Type: RCT Type of Analysis: 'ITT' (but not at follow-up) Blindness: Single blind Duration (days): Mean 98 Followup: 6 months Notes: Randomisation: stratified for previous episodes of depression, presence of dysthymia, sex and marital status. Info on Screening Process: n=323 assessed for eligibility, n=153 excluded (n=133 did not meet the inclusion criteria, and n=20 refused to participate). | n= 170 Age: Mean 37 Sex: 57 males 113 females Diagnosis: 100% Major depression by DSM-IV SCID 15% Dysthymia by DSM-IV SCID Exclusions: No DSM-IV diagnosis of major depression, psychiatric disorders (i.e. bipolar, or psychotic subtypes of depression, panic disorder, current substance misuse, past or present schizophrenia or schizophreniform disorder, organic brain syndrome, or mental retardation). Additionally excluded individuals in some concurrent psychotherapy, receiving psychotic medication, or needed to be hospitalised due to imminent suicide potential or psychosis. Notes: BDI-II score >19 and HRSD-17 score >13 also required. Baseline: CBT REBT Pharmacotherapy | Data Used BDI-II HRSD Leaving study due to side effects Leaving study early for any reason Notes: Scores taken at baseline, 7 weeks, endpoint and 6-month follow-up. | Group 1 N= 57 REBT - maximum of 20 sessions over 14 weeks. Sessions were 50 minutes long, held on an individual basis. Group 2 N= 56 CBT - same schedule and session frequency as REBT intervention. Group 3 N= 57 Pharmacological therapy. Mean dose 50mg/day - Fluoxetine. Starting dose was 10mg/day raising to a maximum 60-80mg/day. Dosage reduced to 20mg/day in weeks 12-14 in 53% of participants who fitted improvement criteria (HRSD<12). Pharmacotherapy sessions lasted around 30 minutes. | Funding support was provided by the Albert Ellis Institute, the National Council for Research and the Romanian Center for Cognitive and Behavioural Psychotherapies. |

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| DERUBEIS2005 | <p>Study Type: RCT Type of Analysis: ITT (with LOCF) Blindness: Single blind Duration (days): Mean 112 Followup: no follow-up Setting: recruited from referrals and from media announcements. Notes: Randomisation: stratified for sex and number of previous episodes. Info on Screening Process: 437 individuals screened, n=197 excluded as they failed to meet inclusion criteria.</p> <p>n= 240 Age: Mean 40 Range 18-70 Sex: 99 males 141 females Diagnosis: 100% Major depression by DSM-IV SCID 53% Anxiety disorder by DSM-IV SCID 25% Dysthymia by DSM-IV SCID</p> <p>Exclusions: <18 or >70 years old, no DSM-IV diagnosis of MDD, non-English speaking. Additional exclusion criteria: history of bipolar disorder, substance misuse/dependence judged to require treatment, current or past psychosis, another Axis I disorder requiring treatment in preference to depression, borderline, antisocial or schizotypal personality disorder, suicide risk, medical condition that contraindicated study medications and nonresponse to an adequate trial of paroxetine in the preceding year.</p> <p>Notes: Additional: HDRS score of >19 at screen and a baseline visit (7 days apart), required for inclusion. Baseline: whole sample: HDRS = 23.4 (2.9).</p> | <p>Data Used</p> <p>Remission on HDRS Response on HDRS Leaving study due to side effects Leaving study early for any reason HDRS (17 item)</p> <p>Notes: HDRS scores reported for 8 weeks (all conditions compared) and 16 weeks (placebo group excluded). Response = HDRS score of <13. Remission = HDRS score of <8</p> | <p>Group 1 N= 60</p> <p>CBT - Delivered by one of 6 therapists (3 on each site). 50-minute sessions held twice weekly for first 4 weeks of treatment, once or twice for the middle 8 weeks and once weekly for the final 4 weeks.</p> <p>Group 2 N= 120</p> <p>Pharmacological therapy. Mean dose 38mg/day - Paroxetine, starting dose 10-20mg/day, increasing to 50mg/day if required for 16 weeks. If poor response after 8 weeks, augmentation with lithium or desipramine was initiated.</p> <p>Group 3 N= 60</p> <p>Placebo - Placebo pills. Given for first 8 weeks of treatment, after this participants were offered another form of treatment.</p> | Supported by grants from the National Institute of Mental Health. Medication and placebo pills supplied by GlaxoSmithKline. |
| DIMIDJIAN2006 | | | | |

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|---------------------|---|---|--|---|
| Study Type: RCT | n= 241 Age: Mean 40 Range 18-60 Sex: 82 males 159 females | Data Used Leaving study due to side effects Leaving study early for any reason BDI-II HDRS (17 item) Data Not Used Cognitive Therapy Scale - not relevant Notes: Response defined as at least 50% reduction from baseline on BDI and HRSD. Remission defined as <8 on BDI and <11 on the HRSD. Available at pre-treatment, 8 weeks, and 16 weeks (endpoint). *relapses also reported in DOBSON2008 | Group 1 N= 45 CBT - CBT delivered by one of three trained psychologists. Maximum of 24, 50 minute sessions over 16 weeks per participant. Sessions generally held twice weekly for the first 8 weeks and once weekly for the next 8 weeks. Group 2 N= 43 Behavioural Activation - Same frequency, schedule and allotment of treatment sessions as in CBT. Group 3 N= 100 Pharmacological therapy. Mean dose 35.17mg/day - Paroxetine with 30-minute clinical management sessions (weekly for first 4 weeks, then biweekly thereafter). Dose started at 10mg/day rising to 50mg/day if required. Group 4 N= 53 Placebo - Placebo given blind with clinical management. Stopped after 8 weeks then participant offered treatment of their choice. | Grant from the National Institute of Mental Health. |
| JACOBSON1996 | | | | 51 |

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|---|---|--------------|------------|----|-----|------------|------------|------------|------|------------|------------|------------|--|---|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT - 'all entering treatment' (LOCF).</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 140</p> <p>Followup: 6 months</p> <p>Setting: 80% of participants referred directly from Group Health Cooperative, 20% recruited from public service announcements.</p> <p>Notes: Randomisation: stratified for number of previous episodes, presence/absence of dysthymia, severity of depression, gender and marital status.</p> <p>Info on Screening Process: Sample consisted of n=152, however n=3 left the study just after randomisation without receiving any treatment.</p> | <p>n= 152</p> <p>Age: Mean 38</p> <p>Sex: 42 males 110 females</p> <p>Diagnosis:</p> <p>100% Major depression by DSM-III-R</p> <p>Exclusions: No DSM-III-R diagnosis of depression, a score of <20 on the BDI and a score of <14 on the HRSD. Further exclusion criteria: a number of concurrent psychiatric disorders (bipolar or psychotic subtypes of depression, panic disorder, current alcohol or other substance misuse, past or present schizophrenia or schizophreniform disorder, organic brain syndrome, and mental retardation), attending some concurrent form of psychotherapy, receiving psychotropic medication or needed to be hospitalised due to imminent suicide potential or psychosis.</p> <p>Notes: Additional score of >13 needed on the HRSD and >19 on the BDI also required for study inclusion.</p> <table border="0" data-bbox="478 605 855 668"> <tr> <td>Baseline: BA</td> <td>AT</td> <td>CT</td> </tr> <tr> <td>BDI</td> <td>29.3 (6.9)</td> <td>29.2 (6.6)</td> <td>29.8 (6.3)</td> </tr> <tr> <td>HRSD</td> <td>17.4 (3.8)</td> <td>19.3 (4.0)</td> <td>19.1 (4.4)</td> </tr> </table> | Baseline: BA | AT | CT | BDI | 29.3 (6.9) | 29.2 (6.6) | 29.8 (6.3) | HRSD | 17.4 (3.8) | 19.3 (4.0) | 19.1 (4.4) | <p>Data Used</p> <p>Improved (measured by DSM) Recovered (HRSD < 8) Recovered (BDI <9) HRSD BDI</p> <p>Data Not Used</p> <p>Expanded Attribution Style Questionnaire - Not relevant Automatic thoughts Questionnaire - Not relevant Pleasant Events Schedule - Not relevant Longitudinal Interval Follow-up Evaluation II - Not relevant</p> <p>Notes: Scores taken at baseline, endpoint and 6 months. Improvement: defined as no longer qualifying for major depressive disorder according to the DSM-III-R.</p> | <p>Group 1 N= 50 CBT - A minimum of eight sessions and a maximum of 20 for each participant. No details of time.</p> <p>Group 2 N= 57 Behavioural Activation - Therapy including only the behavioural activation components of the CBT intervention.</p> <p>Group 3 N= 44 Automatic thoughts - Therapy including the 'automatic thoughts' components of the CBT intervention. Focusing on the activation and the modification of dysfunctional thoughts.</p> | <p>Supported by grants from the National Institute of Mental Health.</p> |
| Baseline: BA | AT | CT | | | | | | | | | | | | | |
| BDI | 29.3 (6.9) | 29.2 (6.6) | 29.8 (6.3) | | | | | | | | | | | | |
| HRSD | 17.4 (3.8) | 19.3 (4.0) | 19.1 (4.4) | | | | | | | | | | | | |
| LUTY2007 | | | | | | | | | | | | | | | |

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|---|---|--|---|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT (with LOCF)</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 96 Range 56-112</p> <p>Followup: Not reported</p> <p>Setting: recruited participants from out patient clinics, GPs, self-referrals and psychiatric emergency services.</p> <p>Notes: randomisation: computer randomised.</p> <p>Info on Screening Process: n=282 screened, n=105 excluded as did not meet the inclusion criteria (n=46), missed interview (n=13), preferred their antidepressant treatment (n=11) or not interested in therapy used in study (n=35)</p> | <p>n= 177</p> <p>Age: Mean 35</p> <p>Sex: 49 males 128 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by DSM-IV SCID 22% Alcohol dependence by DSM-IV 15% Cannabis dependence by DSM-IV 16% Panic disorder by DSM-IV 24% Social phobia by DSM-IV 45% Any Personality Disorder by SCID-PQ 11% Paranoid Personality Disorder by SCID-PQ 27% Avoidant personality disorder by SCID-PQ 11% Borderline Personality Disorder by SCID-PQ 13% Obsessive Personality disorder by SCID-PQ <p>Exclusions: <18 years old, no DSM-IV primary diagnosis of major depression. Medication free for less than 2 weeks, history of mania, schizophrenia, major physical illness that could interfere with treatment or assessment, current alcohol/drug dependence of moderate or greater severity, severe antisocial personality disorder or if participant had failed to respond to one of the two interventions within the last year.</p> | <p>Data Used</p> <ul style="list-style-type: none"> Leaving study early for any reason MADRS change BDI-II endpoint HRSD endpoint MADRS endpoint <p>Data Not Used</p> <ul style="list-style-type: none"> Temperament and Character Inventory - Not relevant MSE endpoint - Not relevant SCL-90 endpoint - Not relevant <p>Notes: Scores on relevant scales taken at baseline and 16-week endpoint. Response defined as 60% reduction in score on MADRS, as well as achieving scores <7 on the HRSD and 10 on the BDI-II. JOYCE2007: Reports MADRS improvement</p> | <p>Group 1 N= 91</p> <p>Interpersonal psychotherapy - Participant booked to see therapist on an approximately weekly basis, for 50 minute sessions for up to 16 weeks. The minimum number of sessions allowed to satisfy the research criteria was 8 and the maximum 19.</p> <p>Group 2 N= 86</p> <p>CBT - Same schedule and time allotment as within the IPT intervention.</p> | <p>Funded by grants from the Health Research Council of New Zealand.</p> |
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| | >29 on MADRS. Baseline: MADRS HRSD BDI-II IPT 23.3 (6.5) 16.0 (4.7) 27.7 (9.4) CBT 24.4 (6.2) 16.7 (4.6) 28.7 (10.4) | | | |
| MANBER2008 | n= 30 Age: Mean 35 Range 18-75 Sex: 12 males 18 females Diagnosis: 100% Major depression by DSM-IV SCID 100% Insomnia by DSM-IV Exclusions: <18 and > 75 years old, No DSM-IV diagnosis of depression and insomnia, scoring <14 on the HRSD-17, not free from psychotropic or hypnotic medication for at least 14 days (45 days for fluoxetine) prior to screening. Further criteria: current suicidal potential, seasonal pattern of MDD, history of treatment with escitalopram or failing at least 2 SSRI trials, conditions incompatible with escitalopram, current ongoing psychotherapy, pharmacotherapy, alternative therapy or any other treatment for insomnia or depression, ten or more arousals of sleep per hour of sleep related to respiratory events, 10 or more limb movements per hour during sleep, meeting ICSID-2 criteria for sleep disorder other than insomnia, uncontrolled medical conditions, abnormal thyroid function or abnormal urine drug screen, inadequate English language fluency. Notes: Additional: a score of >13 on the HRSD-17 was also required for study inclusion. Baseline: HRSD-17: CBT= 19.9 (3.8) , CNTRL = 20.7 (5.8) HRSD-17 minus sleep items: CBT = 15.5 (3.8), CNTRL = 16.7 (5.2) | Data Used HRSD minus sleep items HRSD Data Not Used Insomnia severity index - Not relevant Notes: HRSD scores reported at baseline and at 12 weeks (endpoint), although assessed at 2, 4, 6, and 8 weeks also. | Group 1 N= 15 CBT for Insomnia - 7 individual therapy sessions in CBT concentrating on insomnia and sleeping behaviour. Depression was not addressed. Escitalopram - Starting dose was 5mg/day, increasing to 10mg/day by the second week. Additional increases up to 20mg/day based on clinical response. Medical management included biweekly visits for the first 2 months and a final visit at the end of treatment. Group 2 N= 15 Control - control therapy, including education about sleep and sleeping hygiene. Depression was not addressed Escitalopram - Starting dose was 5mg/day, increasing to 10mg/day by the second week. Additional increases up to 20mg/day based on clinical response. Medical management included biweekly visits for the first 2 months and a final visit at the end of treatment. | Supported by a grant from the National Institute of Mental Health. Forest laboratory provided medication used in the study. |
| MARSHALL2008 | n= 102 Age: Sex: 32 males 70 females Diagnosis: 100% Major depression by DSM-IV SCID 6% Dysthymia by DSM-IV SCID 13% Anxiety disorder by DSM-IV SCID Exclusions: No DSM-IV diagnosis of major depression, scoring <10 on the HRSD, concurrent active medical illness, taking antidepressants within 2 weeks prior to therapy (4 weeks for fluoxetine). Exclusions around other psychiatric history and current psychiatric symptoms are vague. Notes: Additional: A score of 10 or more on the HRSD was required for study entry. Baseline: HRSD: CBT = 17.78 (3.58), IPT = 18.57 (4.06), Pharm = 18.53 (3.58) | Data Used HRSD Data Not Used Self-Criticism assessment - Not relevant Depressive Experiences Questionnaire (DEQ) - Not relevant Notes: Assessments made at baseline and at 16 weeks (endpoint). | Group 1 N= 37 CBT - 16 sessions given weekly (although number of sessions varied based on participant's level of symptomatology). Group 2 N= 35 Interpersonal psychotherapy - 16 sessions given weekly (although number of sessions varied based on participant's level of symptomatology). Group 3 N= 30 Pharmacotherapy + Clinical Management - Prescribed an antidepressant medication selected at treating psychiatrist's discretion. | Supported by an operating grant from the Ontario Mental Health Foundation (OMHF). |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|-----------------------|--|
| ALLADIN2007 | Comparaison not relevant |
| BARKMAN1999 | Dropouts were replaced |
| BEARDSLEE2004 | Not an RCT |
| BHAR2008 | No relevant comparaison, no extractable data. |
| BODENMANN2008 | In couples therapy review |
| DEN BOER2007A | No relevant comparison |
| FAVA2002 | <7 participants in each group |
| FOSTER2007 | No formal diagnosis of depression, no extractable data |
| GONZALEZ2007 | No extractable data |
| HAUTZINGER2004 | Foreign language paper |
| HYER2009 | No relevant outcome measures |
| MCBRIDE2006 | No extractable data |
| PETERSEN2004A | No relevant outcomes |
| SCHATZBERG2005 | Crossover trial |
| SEGAL2005 | Not an RCT |
| SVARTBERG2004 | Less than 50% have formal diagnosis of depression |
| THASE2007 | No blinding in randomisation |
| WARD2000 | Not all sample was depressed. 62% depression |
| WARMERDAM2008 | Drop-out rate =50% |
| WILES2008 | N<10 in one arm. No extractable data. |

References of Included Studies

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 Bagby, R.M., Quily, L.C., Segal, Z.V., McBride, C.C., Kennedy, S.H., & Costa, PT. (2008) Personality and differential treatment response in major depression: A randomized controlled trial comparing cognitive-behavioural therapy and pharmacotherapy. *The Canadian Journal of Psychiatry*, 53, 361-370.
- DAVID2008** (Published Data Only)
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54

112

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Luty, S.E., Carter, J.D., McKenzie, J.M., et al. (2007). Randomised controlled trial of interpersonal psychotherapy and cognitive-behavioural therapy for depression. *British Journal of Psychiatry*, 190, 496-502.

MANBER2008 (Published Data Only)

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Barkman, M., Shapiro, D.A., Hardy, G.E., & Rees, A. (1999) Psychotherapy in two-plus-one sessions: Outcomes of a randomized controlled trial of cognitive-behavioural and psychodynamic-interpersonal therapy for subsyndromal depression. *Journal of Consulting and Clinical Psychology*, 67 (2), 201-211.

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BODENMANN2008 (Published Data Only)

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Cognitive behavioural therapies versus therapies designed for depression - new studies in the guideline update

Comparisons Included in this Clinical Question

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|---|
| Cognitive Therapy vs Integrative Cognitive Therapy |
| CONSTANTINO2008 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|---|---|--|--|
| CONSTANTINO2008 Study Type: RCT Type of Analysis: ITT (LOCF) Blindness: Single blind Duration (days): Range 91-112 Followup: Not reported Setting: Recruited by local advertisements and by referrals from clinics. Notes: Randomisation: no details of procedure. | n= 22 Age: Mean 47 Range 18-65 Sex: 7 males 15 females Diagnosis: 86% Single depressive episode by DSM-IV SCID 14% Recurrent Depression by DSM-IV SCID 41% Dysthymia by DSM-IV SCID Exclusions: <18 and > 65 years old, not meeting DSM-IV criteria for depression, scoring less than 20 on the BDI. Further criteria: history of bipolar or psychotic disorder, currently meeting criteria for borderline personality disorder or substance dependence, unwillingness to terminate other psychosocial treatments for depression, having previous adequate trial of CT for depression, unwillingness to maintain a stable dose of psychotropic medications, imminent suicide risk or presenting serious unstable medical condition. Notes: Additional diagnosis: Scoring at least 20 on the BDI. Baseline: BDI: ICT= 31.18 (6.79) CT= 27.00 (3.19) | Data Used BDI change score BDI Leaving study early for any reason Notes: Assessments were made at baseline and endpoint. | Group 1 N= 11 Cognitive Therapy - Programme consisted of 16 sessions over 13-16 weeks. All sessions were 50 minutes long. The first 6 sessions were conducted twice weekly, and the remaining sessions took place weekly. Group 2 N= 11 Integrative Cognitive Therapy - Grounded in same manual as CT treatment but integrated humanist and interpersonal strategies for addressing and resolving alliance ruptures. Same time scale as CT condition. | Supported by grants from the National Institutes of Health Research Service Award. |

References of Included Studies

- CONSTANTINO2008** (Published Data Only)
Constantino, M.J., Marnell, M.E., Haile, A.J., et al. (2008) Integrative cognitive therapy for depression: A randomized pilot comparison. Psychotherapy: Theory, Research, Practice, Training, 45 (2), 122-134.

Group cognitive behavioural therapies - new studies in the guideline update

Comparisons Included in this Clinical Question

| Group CBT vs Wait list control |
|--------------------------------|
| ALLARTVANDAM2003 |
| DALGARD2006 |
| HARINGSMA2006A |
| WONG2008 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|--|---|--|---|
| ALLARTVANDAM2003 Study Type: RCT Type of Analysis: 'ITT': 102 who had pre/post data Blindness: No mention Duration (days): Mean 84 Followup: 6 months & 12 months Setting: newspaper & TV ads; Netherlands Notes: RANDOMISATION: stratified by sex Info on Screening Process: 324 | n= 110 Age: Mean 46 Sex: 39 males 63 females Diagnosis: 5% Dysthymia by CIDI 95% No formal diagnosis Exclusions: current diagnosis of major depression or lifetime history of bipolar disorder; current psychiatric diagnosis warranting treatment or likely to interfere with participation Notes: 95% had no current diagnosis of depression but BDI ≥ 10 . Demographic (except diagnosis) & efficacy data for 102 participants only. Baseline: BDI: CWD 15.78 (6.89), Control 14.0 (6.9) | Data Used BDI follow-up BDI endpoint Data Not Used General Health Qu'aire - not relevant Automatic Thoughts Questionnaire - not relevant Dutch Personality Qu'aire - not relevant Scale for Interpersonal Behaviour - not relevant Pleasant Events Schedule - not relevant Notes: Follow-up 6m & 12m author emailed 23/05/08 for dropouts in control group & clarification of control intervention | Group 1 N= 68 CWD course - 12 weekly 2 hr sessions with booster session 6 wks after course, sessions consist of lectures, discussions of homework assignments & practical skill training. 8-11 participants & 2 instructors for each group who were trained psychologists or grad students Group 2 N= 42 Control - treatment as usual - free to seek medical/psychological help | Funding: National fund of mental health |
| DALGARD2006 Study Type: RCT Blindness: Single blind Duration (days): Mean 56 Followup: 6m Setting: recruited through newspaper ads; Norway Notes: RANDOMISATION: every 2nd person on list of names in order of recruitment assigned to intervention group, 3 random people moved between groups Info on Screening Process: 300 | n= 155 Age: Mean 47 Sex: 37 males 118 females Diagnosis: 100% Unipolar depression by DSM-IV Exclusions: psychotic symptoms, other psychiatric diagnosis, suicidal ideation, learning disabilities Notes: 44% participants on concurrent medication Baseline: BDI: CWD 21.8 (7.9), control 22.9 (8.2) | Data Used Remission: <10 BDI at 6 months Response: improvement of ≥ 6 points on BDI BDI change score Leaving study early for any reason | Group 1 N= 81 CWD course - 8 weekly 2.5 hour sessions and booster sessions at 1, 2 & 4 months. Took place in primary health clinic, 8-10 participants in each group & led by 2 trained professionals (mainly nurses) Group 2 N= 74 Control - treatment as usual | |
| HARINGSMA2006A | | | | |

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|------------------------------|--|---|--|
| Study Type: RCT | n= 137 | Data Used HADS-A HADS-D HADS-S CES-D | Group 1 N= 21 CWD course - 10 weekly 2 hour sessions in groups of 6-13 participants, Dutch version of CWD course for older adults, instructors were 2 trained health care professional |
| Type of Analysis: completers | Age: Mean 64 Range 55-85 | Data Not Used MOS-SF-20 - not relevant | Group 2 N= 22 Wait list - no psychological treatment, started course after 10 weeks |
| Blindness: No mention | Sex: 34 males 76 females | | |
| Duration (days): Mean 70 | Diagnosis: 35% No axis I disorder by MINI 25% Anxiety disorder by MINI | | |

58

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|--|--|--|--|---------------------------------|
| divided equally Info on Screening Process: 246 | 19% Major depression by MINI 20% Mixed anxiety/depression by MINI Exclusions: <55 years, cognitive impairment, current bipolar disorders, schizophrenia, substance disorder, recent bereavement, hearing impairment, insufficient knowledge of Dutch, receiving other psychotherapy Notes: 137 participants randomly allocated, age & sex info reported for 110 completers, data extracted for 43 participants with diagnosis of MDD or MDD & anxiety Baseline: CWD Waitlist CES-D 31.95 (8.26) 30.91 (8.14) HADS-S 23.65 (6.27) 25.0 (6.16) HADS-D 11.43 (4.25) 12.45(4.19) HADS-A 12.21 (4.27) 12.55 (3.88) | | | |
| WONG2008 Study Type: RCT Type of Analysis: ITT (Last observation carried forward) Blindness: No mention Duration (days): Mean 70 Followup: no follow-up Setting: Participants recruited by referrals or advertisements posted in hospital/psychiatric clinics. Notes: Randomisation: conducted by individual who was independent of the research team, but no further details. Info on Screening Process: n=101 potential participants were recruited. N=3 were not included as they had severely acute depressive symptoms and recent suicide attempts and n=2 were not interested in group therapy. | n= 96 Age: Mean 37 Range 18-60 Sex: 21 males 75 females Diagnosis: 100% Major depression by DSM-IV Exclusions: <18 and > 60 years old, not suffering from major depression (according to the DSM-IV), no mild to severe symptoms of depression measured on the BDI (Chinese version). Further exclusion criteria: Psychosis, severely acute depressive symptoms at the time of the interview or suicide attempt/ideation in the 3 months before the interview. Notes: additional: Mild to severe depressive symptoms as measured on the Chinese version of the BDI (C-BDI) was also required. Baseline: C-BDI: CBT group = 22.8 (10.8), wait list control: 25.0 (10.4). All participants were taking medication at the start of the time of study (mainly TCAs or SSRIs). | Data Used Leaving study early for any reason C-BDI Data Not Used Dysfunctional attitude scale - Not relevant COPE scale - Not relevant Emotions Checklist - Not relevant Notes: Assessments made at baseline and endpoint (10 weeks). | Group 1 N= 48 Group CBT - 10 sessions, each lasting 2.5 hours Group 2 N= 48 Wait list - No treatment given (only received treatment after study had finished) | No notes on funding or support. |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|---|
| STICE2007 | Approx 50% of the population are less than 18 years old |

References of Included Studies

- ALLARTVANDAM2003** (Published Data Only)
Allart-Van Dam, E., Hosman, C. M., Hoogduin, C. A., & Schaap, C. P. (2007) Prevention of depression in subclinically depressed adults: follow-up effects on the 'Coping with Depression' course. Journal of Affective Disorders, 97, 219-228.
Allart-Van Dam, E., Hosman, C. M. H., Hoogduin, C. A. L., & Schaap, C. P. D. R. (2003) The Coping with Depression course: Short-term outcomes and mediating effects of a randomized controlled

trial in the treatment of subclinical depression. Behavior Therapy, 34, 381-396.

DALGARD2006 (Published Data Only)

Dalgard, O. S. (2002) An educational programme for coping with depression: a randomised controlled trial. Tidsskrift for den Norske Laegeforening, 124, 3043-3046.

Dalgard, O. S. (2004) An educational programme for coping with depression: A randomised controlled trial. Tidsskrift for den Norske Laegeforening, 124, 3043-3046.

*Dalgard, O. S. (2006) A randomised controlled trial of a psychoeducational group program for unipolar depression in adults in Norway (NCT00319540). Clinical Practice and Epidemiology in Mental Health, 2, 15.

59

HARINGSMA2006A

(Published Data Only)

Haringsma, R., Engels, G. I., Cuijpers, P., & Spinhoven, P. (2006) Effectiveness of the Coping With Depression (CWD) course for older adults provided by the community-based mental health care system in the Netherlands: a randomized controlled field trial. *International Psychogeriatrics*, 18, 307-325.

WONG2008

(Published Data Only)

*Secondary reference

Wong, D.F.U. (2008) Cognitive and health-related outcomes of group cognitive behavioural treatment for people with depressive symptoms in Hong Kong: Randomized wait-list control study. *Australian and New Zealand Journal of Psychiatry*, 42, 702-711.

Wong, D.F.K. (2008) Cognitive behavioural treatment groups for people with chronic depression in Hong Kong: A randomized wait-list control design. *Depression and Anxiety*, 25, 142-148.

References of Excluded Studies**STICE2007**

(Published Data Only)

Stice, E., Burton, E., Bearman, S.K., Rohde, P. (2007) Randomized trial of a brief depression prevention program: an elusive search for a psychosocial placebo control condition. *Behaviour Research & Therapy*, 45, 863-876.

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Cognitive behavioural therapies - elderly - new studies in the guideline update

Comparisons Included in this Clinical Question

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|-------------|
| CBT vs TAU |
| LAIDLAW2008 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|--|--|--|
| LAIDLAW2008 Study Type: RCT Type of Analysis: ITT (all entering treatment) Blindness: Single blind Duration (days): Mean 126 Followup: 6 months Setting: Participants recruited from primary care and were referred to the study by their GP. Scotland. Notes: Randomisation: computer generated but no stratification. Info on Screening Process: n=115 referred from GPs, n=28 withheld consent, n=43 did not meet criteria. N=44 randomised, n=4 withdrew before treatment commenced. | n= 40 Age: Mean 76 Range 60-92 Sex: 11 males 29 females Diagnosis: 100% Major depression by DSM-IV Exclusions: <60 years old, not DSM-IV diagnosis of depression, not scoring between 7-24 on the HDRS-17, not scoring between 13-28 on the BDI-II, not able to provide written consent and having been prescribed antidepressants within 3 months of the date of referral to the trial. Further criteria: insufficient knowledge of English, significant cognitive impairment as indicated by a score of 22 or more on the MMSE, or having received 6 or more sessions of CBT with a qualified or recognised cognitive therapist in the past and/or currently receiving psychological therapy. Notes: Additional criteria: scoring between 7-24 on the HRSD-17 and scoring between 13-28 on the BDI-II. Baseline: BDI-II HRSD-17 CBT 19.60 (5.22) 11.40 (3.08) TAU 19.50 (5.48) 11.80 (2.84) | Data Used Leaving study early for any reason WHOQoL HDRS (17 item) BDI-II Data Not Used Beck Hopelessness scale - not relevant Geriatric Depression Scale - not relevant Notes: Outcome measures taken at baseline, endpoint, 3-month and 6-month follow-up. | Group 1 N= 20 CBT - on average, participants received 8 sessions (SD= 4.7, range 2-17 sessions)., Group 2 N= 20 TAU - As close to standard care as possible. Could include involvement of GPs, community mental health teams and other mental health services, as well as including antidepressant treatment. | Supported by grant received by the Chief Scientist Office, Scotland. |

References of Included Studies

LAIDLAW2008

(Published Data Only)

Laidlaw, K., Davidson, K., Toner, H., et al (2008) A randomised controlled trial of cognitive behaviour therapy vs treatment as usual in the treatment of mild to moderate late life depression. International Journal of Geriatric Psychiatry, 23, 843-850.

Cognitive behavioural therapies - relapse prevention - new studies in the guideline update

Comparisons Included in this Clinical Question

| Cognitive behavioural therapies vs Placebo + Clinical Management | Cognitive Behavioural therapy vs Clinical Management | Cognitive therapy vs Ads |
|--|--|--------------------------|
| BOCKTING2005 | FAVA1998 PAYKEL2005 | HOLLON2005 PERLIS2002 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|---|---|--|---|
| BOCKTING2005 Study Type: RCT Type of Analysis: completers Blindness: Single blind Duration (days): Mean 56 Followup: 2 years Setting: Recruited at psychiatric centres (31% of sample population) or media announcements (69%). Notes: Randomisation: performed using random permuted blocks, and was stratified by study location and type of aftercare. Concealment: sealed envelopes Info on Screening Process: n=321 assessed, excluded as did not meet entry criteria. | n= 187 Age: Mean 44 Sex: 50 males 137 females Diagnosis: 100% Remission from major depression by DSM-IV 100% At least 2 major depressive episodes by DSM-IV SCID Exclusions: Not currently in remission for over 10 weeks, less than 2 major depressive episodes in past 5 years, mania, hypomania or history of bipolar, any psychotic disorder, organic brain damage, alcohol/drug misuse, predominant anxiety disorder, recent ECT, recent cognitive treatment or current psychotherapy more than twice a month. Notes: Additional criteria: current score of <10 on the HRSD. Baseline: CBT: HRSD-17 score = 3.8 (2.8), TAU: HRSD-17 score = 3.7 (2.9). | Data Used Relapse as measured by the SCID Leaving study early for any reason Data Not Used Everyday problem checklist - not relevant Stressful life events checklist. - not relevant Dysfunctional attitude scale - not relevant Notes: assessments made at baseline, 3, 12 and 24 months. | Group 1 N= 97 Group CBT - Eight, 2 hour sessions, delivered weekly to groups of 7-12 members (mean = 8). Group 2 N= 90 TAU - Naturalistic treatment (including no treatment). No restriction on use of pharmacotherapy. | Supported by grants from the Health Research Development Counsel. |
| FAVA1998 Study Type: RCT Type of Analysis: 'ITT' but n=5 removed from analysis (see below) Blindness: Single blind Duration (days): Mean 140 Followup: 2 years Setting: Participants referred to and treated in the Affective Disorders programme, University of Bologna, Italy. Notes: Randomisation: no details of procedure. N=5 participants removed as they could not be withdrawn from antidepressant treatment. Info on Screening Process: n=45 randomised but n=5 could not be feasibly withdrawn from the antidepressants and were not included in the analysis. | n= 40 Age: Mean 47 Sex: 16 males 24 females Diagnosis: 100% Major depression by RDC 25% GAD by RDC Exclusions: No RDC diagnosis of major depression, <3 episodes of depression, less than 10 weeks in remission according to the RDC (>2 symptoms for depression present), global severity score of <7 for current depressive episode, history of manic, hypomanic or cyclothymic features, active drug/alcohol misuse/dependence according to DSM-IV criteria, history of antecedent dysthymia, active medical illness, unsuccessful response to antidepressant drugs administered by 2 psychiatrists according to a standardised protocol. Notes: Additional: all participants were required to have responded to treatment in order to be included in this study. | Data Used Relapse according to the RDC Data Not Used Paykel Clinical Interview for Depression - Not relevant Notes: Assessment was made at baseline, then 3,6,9,12,15,18,21, and 24 months after treatment Relapse was defined as the occurrence of an RDC defined episode of major depression. | Group 1 N= 20 CBT - 10, 30 minute sessions held biweekly. Pharmacological therapy - Participants had been previously treated for 3-5 months with antidepressants. Drug use was tapered at the rate of 25 mg/day of amitriptyline (or equivalent) until drug was withdrawn. All participants were drug free by the last two sessions. Group 2 N= 20 Clinical Management - Monitoring medication tapering, reviewing clinical status and providing support/advice if needed. 10, 30 minute sessions held biweekly. Pharmacological therapy - Participants had been previously treated for 3-5 months with antidepressants. Drug use was tapered at the rate of 25 mg/day of amitriptyline (or equivalent) until drug was withdrawn. All participants were drug free | Supported by grants from the "Mental Health Project" Istituto Superiore di Sanita, and the "Ministero dell Universita e della Ricerca Scientifica e Technologica" |

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|-------------------|--|---|--|--|---|
| HOLLON2005 | <p>Study Type: RCT</p> <p>Type of Analysis: completers</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 365</p> <p>Followup: 1 year follow up after first 12 months</p> <p>Setting: recruited from referrals and from media announcements.</p> <p>Notes: Randomisation: stratified for sex and number of previous episodes.</p> <p>Info on Screening Process: This sample is taken from the population used in DERUBEIS2005</p> | <p>n= 104</p> <p>Age: Range 18-70</p> <p>Sex: no information</p> <p>Diagnosis:</p> <p>100% Major depression by DSM-IV SCID</p> <p>Exclusions: Not achieving 'response' criteria on the HDRS in the DERUBEIS2005 study. <18 or >70 years old, no DSM-IV diagnosis of MDD, non-English speaking. Additional exclusion criteria: history of bipolar disorder, substance misuse/dependence judged to require treatment, current or past psychosis, another Axis I disorder requiring treatment in preference to depression, borderline, antisocial or schizotypal personality disorder, suicide risk, medical condition that contraindicated study medications and nonresponse to an adequate trial of paroxetine in the preceding year.</p> <p>Notes: Participants in this study were in remission: defined as a score of <13 on the HDRS at the end of the DERUBEIS2005 trial.</p> <p>Baseline: No details of means. All participants scored 12 or less on the HDRS.</p> | <p>Data Used</p> <p>Sustained response</p> <p>Leaving study early for any reason</p> <p>HDRS (17 item)</p> <p>Relapse as measured by the HRSD</p> <p>Notes: Relapse: scoring >13 on the HDRS-17</p> | <p>Group 1 N= 34</p> <p>Pharmacological therapy. Mean dose 38mg/day - Participants continued their antidepressant treatment (paroxetine with augmentation if required). Also had clinical management sessions every 2 weeks for first month, and monthly thereafter.</p> <p>Group 2 N= 35</p> <p>Placebo - placebo pills given. Same schedule as with the active paroxetine intervention</p> <p>Group 3 N= 35</p> <p>CBT - 3 CBT booster session allowed to be taken up during the 12-month continuation phase.</p> | <p>This sample is taken from the population used in DERUBEIS2005. Supported by grants from the National Institute of Mental Health. Medication and placebo pills supplied by GlaxoSmithKline.</p> |
| PAYKEL2005 | <p>Study Type: RCT</p> <p>Type of Analysis: ITT- only for those with follow-up data.</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 140</p> <p>Followup: 6 years</p> <p>Notes: randomisation: assigned by consecutive sealed envelopes. Stratified by centre, previous depressive episodes, length of present illness and severity.</p> <p>Info on Screening Process: No details</p> | <p>n= 158</p> <p>Age: Mean 43 Range 21-65</p> <p>Sex: 80 males 78 females</p> <p>Diagnosis:</p> <p>100% Remission but residual symptoms by DSM-III-R</p> <p>Exclusions: <21 and > 65 years of age, no previous DSM-II-R diagnosis of depression and current status of remission from depression. Bipolar disorder, cyclothymia, definite drug or alcohol dependence, persistent antisocial behaviour or repeated self-harm, dysthymia with onset before age 20 years, borderline personality disorder, IQ below 70, organic brain disorder, previous CBT, other current Axis I disorder or current psychotherapy.</p> <p>Notes: Additional: participants were also required to have a score of >7 on the HDRS, and >8 on the BDI to satisfy criteria for 'residual symptoms'.</p> <p>Baseline: HDRS: CT= 12.1 (2.7), Control: 12.2 (2.9)</p> | <p>Data Used</p> <p>Relapse (measured by DSM)</p> <p>Data Not Used</p> <p>Longitudinal Interval Follow-up Evaluation II - Not relevant</p> <p>Notes: Relapse was defined as meeting DSM-III-R criteria for MDD for a minimum of 1 month.</p> | <p>Group 1 N= 80</p> <p>CBT - participants seen for 16 sessions during 20-week treatment period, plus 2 booster sessions 6-14 weeks later.</p> <p>*This group also received clinical management.</p> <p>Group 2 N= 78</p> <p>Clinical Management - Participants were seen by the study psychiatrist for 30 minutes every 4 weeks during treatment phase, and every 8 weeks during follow-up (48 weeks).</p> | <p>Supported by grants from the Medical Research Council.</p> |
| PERLIS2002 | | | | | |

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| <p>Study Type: RCT</p> <p>Type of Analysis: ITT with LOCF (last observation carried forward)</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 196</p> <p>Followup: no follow-up</p> <p>Notes: Randomisation: procedure not mentioned.</p> | <p>n= 132</p> <p>Age: Mean 40</p> <p>Sex: 60 males 72 females</p> <p>Diagnosis:</p> <p>100% Remission from major depression by DSM-III-R SCID</p> <p>Exclusions: failure to respond to fluoxetine 60mg/day during depressive episode, or treatment resistant (failure to respond to any antidepressant trial). Other criteria included: pregnancy/breast feeding, suicidal risk, serious or unstable medical illness, history of seizure disorder, organic mental</p> | <p>Data Used</p> <p>Leaving study due to side effects Leaving study early for any reason Relapse as measured by the HRSD</p> <p>Data Not Used</p> <p>Social Adjustment Scale - Not relevant Symptom Questionnaire - not relevant</p> | <p>Group 1 N= 66</p> <p>CBT + Fluoxetine. Mean dose 40mg/day - CBT consisted of 12 weekly sessions, followed by 7 bi-weekly sessions. Fluoxetine was increased from 20 mg/day to 40mg/day after first continuation visit.</p> <p>Group 2 N= 66</p> <p>Medication management + Fluoxetine. Mean dose 40mg/day - Fluoxetine was increased from 20 mg/day to 40mg/day after first continuation visit.</p> | <p>Supported in part by a grant from Eli Lilly and Co.</p> <p>63</p> |
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| | <p>disorders, substance use disorders, within last year, schizophrenia, delusional disorder, psychotic disorders, bipolar disorder, current use of psychotropic drugs, evidence of hypothyroidism.</p> <p>Notes: All participants were in remission at time of randomisation. Remission was defined as a score of <8 on the HRSD-17 for at least 3 weeks.</p> <p>Baseline: HRSD-17 prior to Fluoxetine: CT= 19.2 (3.3), MM= 18.3 (2.4). HRSD-17 at randomisation: CT= 4.7 (2.2), MM= 4.5 (2.1).</p> | <p>Notes: Relapse: defined as a score of >14 on the HRSD at two consecutive visits. This was confirmed by a follow-up visit by a 'blind' clinician.</p> | | |
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Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|--------------------------|
| SCOTT2003A | No relevant new outcomes |
| VITTENGL2009 | No relevant outcomes |

References of Included Studies

BOCKTING2005 (Published Data Only)

Bockting, C.L.H., Schene, A.H., et al. (2005) Preventing relapse/recurrence in recurrent depression with cognitive therapy: A randomized controlled trial. *Journal of Consulting and Clinical Psychology*, 73 (4), 647-657.

FAVA1998 (Published Data Only)

Fava, G.A., Ruini, C., Rafanelli, C., Finos, L., Conti, S., Grandi, S. (2004) Six-year outcome of cognitive behaviour therapy for prevention of recurrent depression. *American Journal of Psychiatry*, 161, 1872-1876.

*Fava, G.A., Rafanelli, C., Grandi, S., Conti, S., & Belluardo, P. (1998) Prevention of recurrent depression with cognitive behavioural therapy. *Archives of General Psychiatry*, 55, 816-820.

HOLLON2005 (Published Data Only)

Hollon, S.D., DeRubeis, R.J., Shelton, R.C., et al. (2005) Prevention of relapse following cognitive therapy vs medications in moderate to severe depression. *Archives of General Psychiatry*, 62, 417-422

PAYKEL2005 (Published Data Only)

Paykel, E.S., Scott, J., Cornwall, P.L., et al. (2005) Duration of relapse prevention after cognitive therapy in residual depression: follow-up of controlled trial. *Psychological Medicine*, 35, 59-68.

PERLIS2002 (Published Data Only)

Perlis, R.H., Nierenberg, A.A., Alpert, J.E., et al. (2002) Effects of adding cognitive therapy to fluoxetine dose increase on risk of relapse and residual depressive symptoms in continuation treatment of major depressive disorder. *Journal of Clinical Psychopharmacology*, 22 (5), 474-480.

References of Excluded Studies

SCOTT2003A (Published Data Only)

Scott, J., Palmer, S., Paykel, E., Teasdale, J., & Hayhurst, H. (2003) Use of cognitive therapy for relapse prevention in chronic depression: Cost effectiveness study. *British Journal of Psychiatry*, 182, 221-227.

VITTENGL2009 (Published Data Only)

Vittengl, J.R., Clark, L.A., & Jarrett, R.B. (2009) Deterioration in psychosocial functioning predicts relapse/recurrence after cognitive therapy for depression. *Journal of Affective Disorders*, 112, 135-143.

Cognitive behavioural therapies - mindfulness - relapse prevention - new studies in the guideline update

Comparisons Included in this Clinical Question

| M-BCBT vs Waitlist | MBCT vs antidepressants | MBCT+TAU vs TAU |
|--------------------|-------------------------|-----------------|
| CRANE2008 | KUYKEN2008 | MA2004 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|--|---|--|---|
| CRANE2008 Study Type: RCT Type of Analysis: Completer data on BDI Blindness: Single blind Duration (days): Mean 56 Followup: 2-3 months Setting: Recruited through poster in family practices and other treatment centres. Notes: Randomisation: stratified according to previous episodes and history of suicidality. Randomisation envelopes sealed and conducted by outsider. Info on Screening Process: n=125 expressed and interest in the study, but n=42 were excluded at telephone screen due to exclusion criteria. N=83 invited to further interview, n=68 included and randomised. | n= 68 Age: Mean 45 Range 18-65 Sex: no information Diagnosis: 100% Remission from major depression by MINI Exclusions: <18 and >65 years old, no previous episodes of MDD and no history of an active suicide ideation or a suicide attempt. Not in recovery (more than 1 week of minimal symptoms of MDD in past 8 weeks). Further exclusion criteria: substance misuse, difficulties in reading, speaking or writing fluent English, presence of manic episode in last 6 months, and participants receiving past CBT. Baseline: BDI-II: M-BCBT = 16.58 (14.23) Wait list = 12.78 (9.83). | Data Used BDI-II Leaving study early for any reason Data Not Used Self-Description Questionnaire - Not relevant | Group 1 N= 33 Mindfulness-Based CBT - Programme consisted of an individual pre-class interview followed by eight weekly, 2-hour classes, plus an all-day class between weeks 6 and 7. Group 2 N= 35 Wait list - Wait list control | Supported by a grant from the Wellcome Trust. |
| KUYKEN2008 | | | | |

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| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 56</p> <p>Followup: 15 months</p> <p>Setting: Primary care settings across Devon, England.</p> <p>Notes: Randomisation: computer generated, stratified by patients' symptomatic status at intake assessment on HRSD(asymptomatic = <8 on HRSD, symptomatic = 8+)</p> <p>Info on Screening Process: n=1469 assessed for eligibility, n=533 declined, n=362 not suitable, n=449 did not return contact and n=2 unreachable. N=123 randomised.</p> | <p>n= 123</p> <p>Age: Mean 49 Range 18-80</p> <p>Sex: 29 males 94 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% History of 3+ previous episodes of depression by DSM-IV SCID 100% Remission from major depression by DSM-IV SCID <p>Exclusions: <18 years old, less than 3 previous episodes of depression (DSM-IV criteria), not currently on a therapeutic dose on antidepressants and been so for 6 months, not in remission from previous episode of depression. Further criteria: Comorbid diagnosis of current substance dependence, organic brain damage, current/past psychosis, bipolar disorder, persistent antisocial behaviour, persistent self-injury requiring clinical management, unable to engage with MBCT for physical or practical reasons (physical problems, language difficulties), and formal concurrent psychotherapy.</p> <table border="0" data-bbox="471 699 786 770"> <tr> <td>Baseline: MBCT</td> <td>ADs</td> </tr> <tr> <td>HRSD: 5.62 (4.3)</td> <td>5.76 (4.69)</td> </tr> <tr> <td>BDI-II: 18.51 (10.91)</td> <td>20.15 (12.86)</td> </tr> </table> | Baseline: MBCT | ADs | HRSD: 5.62 (4.3) | 5.76 (4.69) | BDI-II: 18.51 (10.91) | 20.15 (12.86) | <p>Data Used</p> <p>WHOQoL</p> <p>Leaving study early for any reason</p> <p>BDI-II</p> <p>HDRS (17 item)</p> <p>Service Use and Costs</p> <p>Severity of relapse</p> <p>Time until relapse</p> <p>Notes: Relapse= meeting DSM-SCID criteria for a depressive episode.</p> | <p>Group 1 N= 61</p> <p>MBCT - Mindfulness-based cognitive therapy. Groups of 9-15 participants, 2-hour sessions over 8 consecutive weeks, followed up by four follow-up sessions in the following year. This intervention also included antidepressant tapering/discontinuation.</p> <p>Group 2 N= 62</p> <p>Pharmacological therapy - Continued antidepressant therapy for duration of the trial. Participants were monitored and treated by their primary care physicians.</p> | <p>Funded by the UK Medical Research Council.</p> |
| Baseline: MBCT | ADs | | | | | | | | | |
| HRSD: 5.62 (4.3) | 5.76 (4.69) | | | | | | | | | |
| BDI-II: 18.51 (10.91) | 20.15 (12.86) | | | | | | | | | |
| MA2004 | | | | 0.0 | | | | | | |

| | | | | |
|---|--|--|--|-------------------------------|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT - 'attending sufficient treatment sessions'</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 56</p> <p>Followup: 1 year</p> <p>Setting: Recruited through GPs and advertisements.</p> <p>Notes: Randomisation: by independent statistician. Stratified by severity of last relapse and number of previous episodes.</p> <p>Info on Screening Process: n=76 met inclusion criteria, but n=1 declined. n=75 were randomised.</p> | <p>n= 75</p> <p>Age: Mean 44</p> <p>Sex: 18 males 57 females</p> <p>Diagnosis:</p> <p>100% Remission from major depression by DSM-IV</p> <p>Exclusions: <18 and >65 years of age, no DSM diagnosis of a history of recurrent MDD (2 or more episodes), no depressive episodes in past 2 years, no history of treatment with antidepressant medication, being on antidepressant medication, scoring more than 10 on the HAM-D. Further criteria: History of schizophrenia or schizoaffective disorder, current substance misuse, borderline personality disorder, organic mental disorder or developmental delay, dysthymia before age of 20, current eating disorder, OCD, more than 4 sessions of CBT in lifetime and current psychotherapy/counselling.</p> <p>Notes: Additional: a score of less than 10 on the HAM-D was also required for entry.</p> <p>Baseline: HAM-D: TAU = 5.68 (2.97), MBCT = 5.70 (3.02); BDI: TAU = 15.13 (9.51), MBCT = 13.49 (7.16)</p> | <p>Data Used</p> <p>Relapse as measured by the SCID</p> <p>Leaving study early for any reason</p> <p>Notes: Relapse: defined as meeting DSM-IV-SCID criteria for major depressive episode by a blind interviewer (psychologist).</p> | <p>Group 1 N= 37</p> <p>MBCT - 8 weekly sessions lasting 2 hours. Up to 12 participants per group. Two follow-up sessions were scheduled for intervals of 1 and 6 months.</p> <p>TAU - Participants told to seek help from family doctor or other sources. Monitored at 3 month assessment sessions.</p> <p>Group 2 N= 38</p> <p>TAU - Participants told to seek help from family doctor or other sources. Monitored at 3 month assessment sessions.</p> | <p>No details on funding.</p> |
|---|--|--|--|-------------------------------|

References of Included Studies

CRANE2008 (Published Data Only)

Crane, C., Barnhofer, T., Duggan, D.S., Hepburn, S., Fennell, M.V., & Williams, J.M.G. (2008) Mindfulness-based cognitive therapy and self-discrepancy in recovered depressed patients with a history of depression and suicidality. *Cognitive Therapy Research*, 32, 775-787.

KUYKEN2008 (Published Data Only)

Kuyken, W., Byford, S., Taylor, R.S., et al. (2008) Mindfulness-based cognitive therapy to prevent relapse in recurrent depression. *Journal of Consulting and Clinical Psychology*, 76 (6), 966-978.

MA2004 (Published Data Only)

Ma, S.H., & Teasdale, J.D. (2004) Mindfulness-based cognitive therapy for depression: Replication and exploration of differential relapse prevention effects. *Journal of Consulting and Clinical Psychology*, 72 (1), 31-40.

Group cognitive behavioural therapies - relapse prevention - elderly - new studies in the guideline update

Comparisons Included in this Clinical Question

| |
|------------------------|
| Group CBT + TAU vs TAU |
| WILKINSON2009 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|---|--|---|---|
| WILKINSON2009 Study Type: RCT Type of Analysis: completers Blindness: Single blind Duration (days): Mean 56 Followup: 12 months Setting: recruited from GP surgeries and psychiatric services in Oxford and Southampton, UK. Notes: Randomisation: Computer generated, balanced according to age, sex, length of illness, care level and centre of recruitment. Info on Screening Process: n=79 assessed, n=34 excluded as did not meet the criteria or refused to participate. n=45 randomised, n=5 did not start treatment. | n= 45 Age: Mean 74 Range 60-88 Sex: 17 males 28 females Diagnosis: 100% Remission from major depression by ICD-10 Exclusions: <60 years of age, had not experienced previous episode of depression, had not remitted in last 2 months after taking antidepressant medication. Scoring >10 on the MADRS. Further exclusion criteria: scoring less than 24 on the MMSE, current severe alcohol problems and a diagnosis of bipolar disorder. Notes: Additional criteria: scoring less than 10 on the MADRS also required for inclusion. Baseline: MADRS: CBT-G = 4 (5.4), Control= 6 (5.8) | Data Used Recurrence on MADRS Recurrence on BDI BDI change score MADRS change Notes: recurrence of depression: score of 10 or more on the MADRS and 12 or more on the BDI. Scores taken at 6 and 12 month follow-up. | Group 1 N= 23 Group CBT + TAU - CBT= eight, 90 minute sessions.Treatment as usual (e.g. follow-up by GP or community mental health team). Group 2 N= 22 TAU - Treatment as usual (e.g. follow-up by GP or community mental health team). | Supported by grants from the health foundation. |

References of Included Studies

- WILKINSON2009** (Published Data Only)
 Wilkinson, P., Alder, N., Juszczak, E., et al. (2009) A pilot randomised controlled trial of a brief cognitive behavioural group intervention to reduce recurrence rates in late life depression. International Journal of Geriatric Psychiatry, 24, 68-75.

Behaviour therapy (BT) - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes |
|----------------------|--|--|--|------------------------------|---|
| McLean 1979 (Can) | Allocation: random (no details). Duration: 10 weeks (8-12 sessions) | Outpatients. N=196, 72% women, mean age 39.2 years (+10.9) Diagnosis: Feighner criteria for clinical depression | 1. Short-term psychotherapy 2. Relaxation therapy 3. Behaviour therapy 4. Drug therapy (amitriptyline 75g up to 150mg (Data not extracted) | 1.Leaving the study early | No description of therapists - all received pre-treatment training. NB: partners encouraged to attend treatment. Dropouts were replaced, and not clear if replacements were randomised. |

Characteristics of excluded studies

| Study | Reason for exclusion |
|---------------------|----------------------|
| Antonuccio1984 (US) | No control group |

| | |
|--------------------|---|
| Lichtenberg1996 US | Not randomised - participants assigned in cohorts |
| McNamara1986 | No evidence that depression diagnosis made according to recognised criteria |
| Schulz1999 (Ger) | Not randomised |
| Teri1986 (US) | 27% in concurrent treatment for depression |

68

140

Behaviour therapy/ behavioural activation - new studies in the guideline update

Comparisons Included in this Clinical Question

| | | |
|---|--|---|
| Behaviour Activation vs Supportive Therapy HOPKO2003 | Cognitive therapy vs Behaviour Activation vs ADs vs Placebo DIMIDJIAN2006 | Cognitive therapy vs Behavioural Activation component vs Automatic Thoughts condition JACOBSON1996 |
|---|--|---|

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|---|---|--|---|
| DIMIDJIAN2006 Study Type: RCT Type of Analysis: ITT Blindness: Single blind Duration (days): Mean 112 Followup: Not reported Setting: Recruitment from media advertisements (n=150, 62%), referral from local agencies (n=64, 27%) and word of mouth/other referral (n=27, 11%). Notes: randomisation: computer generated list. Severity of depression was used as a stratification variable. Info on Screening Process: initial intake n=388, n=147 declined or did not meet research criteria. | n= 241 Age: Mean 40 Range 18-60 Sex: 82 males 159 females Diagnosis: 100% Major depression by DSM-IV SCID Exclusions: <18 or >65, lifetime diagnosis of psychosis or bipolar disorder, organic brain syndrome, or mental retardation. Substantial or imminent suicide risk; a current (within 6 months) or primary diagnosis of alcohol/drug misuse/dependence or a positive toxicology screen; primary diagnosis of panic disorder, OCD, pain disorder, anorexia, or bulimia, presence of antisocial, borderline or schizotypal PD. In addition, participants who had not responded favourably within the last year to CT or paroxetine. Participants were excluded if they had an unstable medical condition, were pregnant, lactating or not using suitable contraception. Notes: Diagnosis: score >19 on BDI-II and >13 on the HAMD-17 additional to DSM diagnosis. Low severity = score of 14-19 on HAMD-17 High severity = scored >19 on HAMD-17 Baseline: Low severity: HAMD-17; CT = 16.65 (1.84), BA = 17.28 (1.45), AntiD = 16.98 (1.60), PLB = 16.68 (1.86); BDI-II; CT = 27.30 (6.89), BA = 28.72 (4.59), AntiD = 23.79 (2.60), PLB = 24.32 (3.69) High severity: HAMD-17; CT = 22.72 (2.61), BA = 23.16 (2.53), AntiD = 23.79 (2.60), PLB = 24.32 (3.69) BDI-II; CT = 34.12 (5.67), BA = 36.68 (5.91), AntiD = 35.61 (7.13), PLB = 34.55 (8.36) | Data Used Leaving study due to side effects Leaving study early for any reason BDI-II HDRS (17 item) Data Not Used Cognitive Therapy Scale - not relevant Notes: Response defined as at least 50% reduction from baseline on BDI and HRSD. Remission defined as <8 on BDI and <11 on the HRSD. Available at pre-treatment, 8 weeks, and 16 weeks (endpoint). *relapses also reported in DOBSON2008 | Group 1 N= 45 CBT - CBT delivered by one of three trained psychologists. Maximum of 24, 50 minute sessions over 16 weeks per participant. Sessions generally held twice weekly for the first 8 weeks and once weekly for the next 8 weeks. Group 2 N= 43 Behavioural Activation - Same frequency, schedule and allotment of treatment sessions as in CBT. Group 3 N= 100 Pharmacological therapy. Mean dose 35.17mg/day - Paroxetine with 30-minute clinical management sessions (weekly for first 4 weeks, then biweekly thereafter). Dose started at 10mg/day rising to 50mg/day if required. Group 4 N= 53 Placebo - Placebo given blind with clinical management. Stopped after 8 weeks then participant offered treatment of their choice. | Grant from the National Institute of Mental Health. |
| HOPKO2003 | | | | |

| | | | | |
|---|---|------------------------------------|--|---|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: No mention</p> <p>Duration (days): Mean 14</p> <p>Setting: Hospitalised patients in West Virginia hospital.</p> <p>Notes: Randomisation: No details</p> | <p>n= 25</p> <p>Age: Mean 30</p> <p>Sex: 16 males 9 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by Unstructured Diagnostic Interview by Psychiatrist 40% Anxiety disorder by Unstructured Diagnostic Interview by Psychiatrist 44% Substance misuse/dependence by Unstructured Diagnostic Interview by Psychiatrist <p>Exclusions: Not having a principal diagnosis of depression, having a history of or current psychosis</p> | <p>Data Used</p> <p>BDI</p> | <p>Group 1 N= 10</p> <p>Behavioural Activation - Participants were seen 3 times per week for approximately 20 minutes by the clinician.</p> <p>Group 2 N= 15</p> <p>Supportive Psychotherapy - Participants met with a clinician 3 times per week, for approximately 20 minutes. This involved a nondirective discussion with the clinician, encouraging the sharing of experiences.</p> | <p>No details on funding.</p> <p>69</p> |
|---|---|------------------------------------|--|---|

| | Baseline: BDI: BA= 35.1 (7.4) SP= 37.1 (15.4) | | | | | | | | | | | | | | | |
|---------------------|---|------------|------------|----|----|-----|------------|------------|------------|------|------------|------------|------------|---|--|---|
| JACOBSON1996 | <p>Study Type: RCT</p> <p>Type of Analysis: ITT- 'all entering treatment' (LOCF).</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 140</p> <p>Followup: 6 months</p> <p>Setting: 80% of participants referred directly from Group Health Cooperative, 20% recruited from public service announcements.</p> <p>Notes: Randomisation: stratified for number of previous episodes, presence/absence of dysthymia, severity of depression, gender and marital status.</p> <p>Info on Screening Process: Sample consisted of n=152, however n=3 left the study just after randomisation without receiving any treatment.</p> <p>n= 152 Age: Mean 38 Sex: 42 males 110 females</p> <p>Diagnosis: 100% Major depression by DSM-III-R</p> <p>Exclusions: No DSM-III-R diagnosis of depression, a score of <20 on the BDI and a score of <14 on the HRSD. Further exclusion criteria: a number of concurrent psychiatric disorders (bipolar or psychotic subtypes of depression, panic disorder, current alcohol or other substance misuse, past or present schizophrenia or schizophreniform disorder, organic brain syndrome, and mental retardation), attending some concurrent form of psychotherapy, receiving psychotropic medication or needed to be hospitalised due to imminent suicide potential or psychosis.</p> <p>Notes: Additional score of >13 needed on the HRSD and >19 on the BDI also required for study inclusion.</p> <table> <thead> <tr> <th>Baseline:</th> <th>BA</th> <th>AT</th> <th>CT</th> </tr> </thead> <tbody> <tr> <td>BDI</td> <td>29.3 (6.9)</td> <td>29.2 (6.6)</td> <td>29.8 (6.3)</td> </tr> <tr> <td>HRSD</td> <td>17.4 (3.8)</td> <td>19.3 (4.0)</td> <td>19.1 (4.4)</td> </tr> </tbody> </table> | Baseline: | BA | AT | CT | BDI | 29.3 (6.9) | 29.2 (6.6) | 29.8 (6.3) | HRSD | 17.4 (3.8) | 19.3 (4.0) | 19.1 (4.4) | <p>Data Used</p> <ul style="list-style-type: none"> Improved (measured by DSM) Recovered (HRSD < 8) Recovered (BDI <9) HRSD BDI <p>Data Not Used</p> <ul style="list-style-type: none"> Expanded Attribution Style Questionnaire - Not relevant Automatic thoughts Questionnaire - Not relevant Pleasant Events Schedule - Not relevant Longitudinal Interval Follow-up Evaluation II - Not relevant <p>Notes: Scores taken at baseline, endpoint and 6 months. Improvement: defined as no longer qualifying for major depressive disorder according to the DSM-III-R.</p> | <p>Group 1 N= 50</p> <p>CBT - A minimum of eight sessions and a maximum of 20 for each participant. No details of time.</p> <p>Group 2 N= 57</p> <p>Behavioural Activation - Therapy including only the behavioural activation components of the CBT intervention.</p> <p>Group 3 N= 44</p> <p>Automatic thoughts - Therapy including the 'automatic thoughts' components of the CBT intervention. Focusing on the activation and the modification of dysfunctional thoughts.</p> | Supported by grants from the National Institute of Mental Health. |
| Baseline: | BA | AT | CT | | | | | | | | | | | | | |
| BDI | 29.3 (6.9) | 29.2 (6.6) | 29.8 (6.3) | | | | | | | | | | | | | |
| HRSD | 17.4 (3.8) | 19.3 (4.0) | 19.1 (4.4) | | | | | | | | | | | | | |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|----------------------|
| CULLEN2006 | No extractable data |

References of Included Studies

- DIMIDJIAN2006** (Published Data Only)
Dobson, K.S., Hollon, S.D., Dimidjian, S., et al. (2008) Randomized trial of behavioural activation, cognitive therapy, and antidepressant medication in the prevention of relapse and recurrence in major depression. *Journal of Consulting and Clinical Psychology*, 76 (3), 468-477.
- *Dimidjian, S., Hollon, S.D., Dobson, K.S., Schmalong, K.B., et al. (2006) Randomized trial of behavioural activation, cognitive therapy, and antidepressant medication in the acute treatment of adults with major depression. *Journal of Consulting and Clinical Psychology*, 74 (4), 658-670.

- HOPKO2003** (Published Data Only)
Hopko, D.R., Lejuez, C.W., LePage, J.P., Hopko, S.D., & McNeil, D.W. (2003) A brief behavioural activation treatment for depression. *Behaviour Modification*, 27 (4), 458-469.
- JACOBSON1996** (Published Data Only)
Jacobson, N.S., Dobson, K.S., Truax, P.A., et al. (1996) A component analysis of cognitive-behavioural treatment for depression. *Journal of Consulting and Clinical Psychology*, 64 (2), 295-304.

References of Excluded Studies

- CULLEN2006** (Published Data Only)
Cullen, J.M., Spates, C.R., & Doran, N. (2006) Behavioural activation treatment for major depressive disorder: A pilot investigation. *The Behaviour Analyst Today*, 7(1), 151-166.

Problem solving - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|-------|---------|--------------|---------------|----------|-------|----|
|-------|---------|--------------|---------------|----------|-------|----|

| | | | | | | |
|-----------------------|---|---|---|---|---|---|
| Mynors-Wallis 1995 | Allocation: Random using sealed envelopes, stratified by severity of disorder. Duration: six 30-minute sessions over 3 months. | Recruited from GPs. N=91, 70 female, mean age 37 years. Diagnosis: RDC criteria for major depression, HRSD>13. | 1. Problem solving 2. Amitriptyline 150 mg/day 3. Placebo | 1. Leaving the study early for any reason (based on number of participants not achieving 6 sessions) 2. HRSD mean endpoint scores 3. BDI mean endpoint scores 4. Leaving the study early due to side effects 5. BDI > 8 6. HRSD >7 | Therapists were 1 psychiatrist experienced in PS and 2 GPs who received training. Continuous data extracted for all patients completing at least 4 sessions | A |
|-----------------------|---|---|---|---|---|---|

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|--------------------|--|---|---|---|--|---|
| | | | | | | |
| Mynors-Wallis 2000 | Allocation: Random using sealed envelopes, generated using list of random numbers, stratified for severity. Duration: 6 fortnightly sessions, plus 1-year follow up (from start of study) | Referrals from GPs. N=151, 116 female, mean age 35. Diagnosis: Probable or definite major depression on research diagnostic criteria. HRSD > 13. Minimum 4 weeks' illness. | 1. Problem solving / GP 2. Problem solving / practice nurse 3. AD: Fluvoxamine (n=7*, 100-150 mg) or paroxetine (n=64*, 10-40mg (most at 20mg). 4. PS sessions with nurse + AD (1 and 2 added together for dichotomous outcomes; 1 entered for continuous outcomes) * N for AD alone and in combination | 1. HRSD mean scores at endpoint and 1-year follow-up 2. BDI mean endpoint scores at endpoint and 1-year follow-up 3. Leaving the study early for any reason 4. Leaving the study early due to side effects 5. HRSD > 7 at endpoint and 1-year follow-up | Therapists were 3 research GPs and 2 research practice nurses. All followed treatment manual and had supervision from an experienced PS therapist who was also the author. | A |

Characteristics of excluded studies

| Study | Reason for exclusion |
|------------------|--|
| Alexopoulos2003 | Participants with executive dysfunction |
| Catalan1991 (UK) | Patients not necessarily depressed |
| Dowrick2000 | Patients not all depressed. Some patients with adjustment disorder |
| Garland2000 (UK) | Not an RCT |
| Lynch1997 (US) | Not clear what treatment was received by comparison group; dropout figures for comparison group not clear; BDI data from < 50% treatment group; SDs for HRSD scores not calculable |
| Shipley1973 (US) | Not randomised |
| Simons2001(UK) | Preliminary report - no results given |
| Unutzer2001 | Not all participants in treatment group received problem-solving therapy; also, no extractable outcomes |

| | |
|---------------|--|
| Williams2000 | Participants have diagnosis of dysthymia or minor depression |
| Wood1997 (UK) | Participants do not have primary diagnosis of depression |

72

Problem solving - studies excluded in the guideline update

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|---|
| AREAN2008 | No relevant outcomes, no extractable data |
| NEZU1986 | n<10 in one arm |

References of Excluded Studies

AREAN2008

Arean, P., Hegel, M., Vannoy, S., Fan, M., & Unutzer, J. (2008) Effectiveness of problem-solving therapy for older, primary care patients with depression: Results from the IMPACT project. *The Gerontologist*, 48 (3), 311-323.

NEZU1986

(Published Data Only)

Nezu, A.M. (1986) Efficacy of a social problem-solving therapy approach for unipolar depression. *Journal of Consulting and Clinical Psychology*, 54 (2), 196-202.

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Couples therapy - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|-------|---------|--------------|---------------|----------|-------|----|
|-------|---------|--------------|---------------|----------|-------|----|

| | | | | | | |
|--------------------|---|--|---|-------------------------------|--|---|
| Beach 1992 (US) | Allocation: random (no details) Duration: 15 weeks. CT = 15-20 sessions | Couples with marital difficulties recruited via press advertisements. N = 45 couples Diagnosis: women only - DSM- III for major depression or dysthymia . | 1 CT for wife - following Beck et al (1979) 2. Behavioural marital therapy (BMT) 3. Waiting list - treatment on demand (3 hours' crisis intervention if required) - no couples requested this | 1.BDI mean endpoint scores | CT & BMT: 4 therapists were doctoral level psychologists and 2 advanced graduate students in clinical psychology. All had > 4 years' full-time graduate training in clinical psychology & 30 hours in each of the 2 treatments by nationally recognised experts. | B |
|--------------------|---|--|---|-------------------------------|--|---|

| | | | | | | |
|--------------------------|---|--|---|--|--|---|
| Emanuels - Zuurveen 1996 | Allocation: random (no further details) Duration: 16 weeks, weekly 1-hour sessions | Outpatients recruited via the press (except 3 - not clear if only in pre-randomised group) N = 36. Age (after dropouts, n=9): Patients: mean 38.4 (SD =9.6) Spouses/partners: mean 38.2 (SD = 8.6). Mean duration of marriage/relationship: 13.8 years (SD = 8.5). Diagnosis: depression DSM-III-R Marital distress, MMQ >=40 | 1. Individual CBT-based on Lewisohn's behavioural approach & Beck's CBT. 1 st session: link between activity level & mood explained, identified pleasant events. Sessions 2-8: Principle of scheduling & graded task assignments explained. Pleasant activities /mastery-related events scheduled. Session 5 onwards shift to social skills e.g. assertion & communication skills, including relevant homework. Sessions 9-16: cognitive therapy - influence of thoughts on mood & behaviour, including challenging assumptions. N=14 2. Behavioural marital therapy: based on Beach et al (1990), Emmelkamp et al (1984) and Emmelkamp (1988). N=13. | 1. Leaving the study early 2. BDI mean endpoint scores | Therapists: advanced clinical psychology students, who had completed advanced courses in CBT. Also, a marital therapist who had completed a course in behavioural marital therapy. Before study all had extensive training in relevant treatment manuals. All sessions were recorded on audiotape and overheard by member of research team. Supervisions were held twice a week with groups of 2-5 therapists. | B |
| Foley 1989 (US) | Allocation: random (no details) Duration: 16 weekly sessions. | Allocation: random (no details) Duration: 16 weekly sessions. Disputes as a major problem included. | 1. Conjoint marital IPT 2. Individual IPT Both following treatment manuals developed for the study | 1. HRSD mean endpoint scores 2. Leaving the study early | IPT - CM: 3 therapists all social workers. Individual IPT: 3 therapists; a psychiatrist, a psychologist and a social worker. All therapists were trained using treatment manuals. | B |
| O'Leary 1990 (US) | Allocation: random (no details). Duration: 16 weekly sessions + unspecified follow-up period. | Married couples with depressed wife describing themselves as maritally discordant. N=36; average age of wives 39.3 years. Wife diagnosed using DSM-III for major depression or dysthymia (n=4) and BDI > 13. | 1. Behavioural marital therapy 2. Individual CBT 3. Waitlist control (WLC) | 1. BDI mean scores (SDs calculated from F ratios; not available for marital vs CBT at end of treatment, or marital vs WLC, or CBT vs WLC at follow-up). 2. Leaving the study early. | Therapists: 2 doctoral level psychologists & 1 5th-year graduate student in clinical psychology. All had >4 years full-time graduate training in clinical psychology, +1-semester behavioural marital therapy seminar and 1-year practicum. Also, had 30 hours' training in each of the two treatments, specifically for this study. | B |

Characteristics of excluded studies

| Study | Reason for exclusion |
|-------------------|---|
| Beach1986 (US) | Very small study (n=8); not clear to which groups dropouts allocated; 4/6 end-point BDI scores given (i.e. IPD) = 0 - hard to believe |
| Crowe1978 | Patients not identified as being depressed |
| Friedman1975 | Irrelevant outcomes reported; dropouts only given for 4 weeks (study length 12 weeks) |
| Jacobson1991 (US) | Data reported by maritally distressed vs maritally non-distressed, with no combined data available. |
| O'Leary1981 (US) | Patients not exclusively depressed; no useable data |

| | |
|-------------------|---|
| Snyder1989 | No primary diagnosis of depression |
| Teichman1995 (Is) | >20% of participants diagnosed with dysthymia (21/45) |
| Waring1988 (Can) | Not clear if participants were randomised; 4-arm trial (2 levels of psychotherapy & 2 of pharmacotherapy), outcome data given by psychotherapy only |
| Waring1990 (Can) | Patients treated for marital distress not depression |
| Waring1991 (Can) | Patients treated for marital distress not depression |

Couples therapy - new studies in the guideline update

Comparisons Included in this Clinical Question

| | |
|---|-------------------------------|
| Couples therapy vs CBT vs Couples therapy + CBT | Couples therapy vs CBT vs IPT |
| JACOBSON1993 | BODENMANN2008 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|---|--|---|
| BODENMANN2008 Study Type: RCT Type of Analysis: Not clear Blindness: Single blind Duration (days): Mean 140 Followup: 18 months Setting: Recruited through media and medical practices. Notes: Randomisation: block randomisation to ensure an equal allocation of 10 couples to each group. Info on Screening Process: n=428 screened, 27% did not reach inclusion criteria with regard to symptomatology, 39% were single with no close relationship, 18% had partners unwilling to participate, 13% were older than 60 years old, 3% could not speak sufficient German. | n= 60 Age: Mean 45 Sex: 25 males 35 females Diagnosis: 75% Major depression by DSM-IV SCID 25% Dysthymia by DSM-IV SCID Exclusions: Excluded from study if they were older than 60 years, had bipolar disorder, psychotic or manic symptoms, or secondary depression or if they were highly suicidal. Also being single/no close relationship and not speaking German to sufficient level were grounds for exclusion. Notes: Additional: Participants had to score >17 on the BDI for inclusion. Baseline: CBT IPT Couples BDI 26.05 (8.18) 24.75 (6.03) 24.70 (7.18) HRSD 14.15 (6.39) 13.95 (3.36) 16.2 (6.88) | Data Used HRSD change score BDI change score Data Not Used Dyadic Coping Inventory (DCI) - Not relevant Partnership Questionnaire - No relevant Notes: Measurements on BDI taken at pretest, post-test (2 weeks after treatment), 6 months, 1 year and 1.5 years. Measurement on HRSD taken at pretest and post-test. | Group 1 N= 20 Couples therapy - 10 two-hour sessions, every 2 weeks. Group 2 N= 20 Interpersonal psychotherapy - 20 1-hour sessions, on a weekly basis. Group 3 N= 20 CBT - 20 1-hour sessions, on a weekly basis. | Supported by Swiss National Science Foundation Research Grants. |
| JACOBSON1993 Study Type: Study Description: SEE JACOBSON1991 (previous guideline) FOR STUDY DETAILS Blindness: Duration (days): | | | | |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|--------------------------|
| LEFF2000 | >50% drop out in one arm |

References of Included Studies

BODENMANN2008 (Published Data Only)

Bodenmann, G., Plancherel, B., Beach, S.R., et al. (2008) Effects of coping-oriented couples therapy on depression: A randomized clinical trial. Journal of Consulting and Clinical Psychology, 76, (6),

944-954.

JACOBSON1993 (Published Data Only)

Jacobson, N.S., Fruzzetti, A.E., Dobson, K., Whisman, M., & Hops, H. (1993) Couple therapy as a treatment for depression: II. The effects of relationship quality and therapy on depressive relapse. Journal of Consulting and Clinical Psychology, 61 (3), 516-519.

References of Excluded Studies

77

LEFF2000

Leff, J., Vearnals, S., Brewin, C.R., et al. (2000). The London Depression Intervention trial: randomised controlled trial of antidepressants v. couple therapy in the treatment and maintenance of people

160

with depression living with a partner: Clinical outcomes and costs. *British Journal of Psychiatry*, 177, 95-100.

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Interpersonal therapy (IPT) - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|-------|---------|--------------|---------------|----------|-------|----|
|-------|---------|--------------|---------------|----------|-------|----|

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|----------------------------|---|--|---|--|--|---|
| de Mello 2001 (Braz) | Allocation: random (stratified by gender and early or late onset) Duration: 48-weeks: IPT: 16 weekly sessions + 6 monthly booster sessions; AD: 8 months | Participants referred to psychiatric outpatient clinics and a teaching hospital N = 35, female 28, age range 20-60. Diagnosis: ICD-10 for dysthymia (N=32 had double depression) | 1. IPT + Moclobemide - IPT adapted to dysthymia; focus on grief, role dispute, role transition, or interpersonal deficits 2. Moclobemide + routine care - for 8 months; 150 mg during first week & 300 mg thereafter. During clinical consultations, patients received unstructured psychoeducation and clinical assessments | 1. HRSD mean endpoint scores at 12 and 48 weeks 2. Leaving the study early for any reason (NB during whole study period) 3. Leaving the study early due to side effects ('medication intolerance') | Therapist was a psychiatrist with psychotherapy experience, training acquired by reading IPT material, attending an IPT course and contacts with IPT therapist | A |
| Elkin 1989 (US) | Allocation: random (no details) Duration: 16 weeks - CBT 12 | Outpatients N = 239, age 21-60 years. Diagnosis: RDC | 1.CBT-following Beck et al (1979) 2. IPT - aims to help patients | 1. BDI mean endpoint scores | Therapists were different group of experienced therapists for each | B |

| | | | | | | |
|-----------------|---|---|---|--|--|---|
| | sessions in 1st 8 weeks, then 8 sessions once a week (20 sessions in total), IPT - 16 weekly sessions with optional 4 additional sessions at therapist discretion (all psychotherapy sessions 50 minutes); imipramine-CM and P-CM groups 16 weekly sessions with one or two additional tapering-off sessions, initial pharmacotherapy session 45-60 minutes long, remaining sessions 20-30 minutes. | criteria for definite major depression, HRSD ≥ 14 . | achieve a better understanding of their interpersonal problems & improve social functioning. 3. Imipramine-CM -flexible dose schedule with general goal of achieving 200mg/day by 3rd week, may be increased to 300 mg/day. Administered within context of clinical management sessions, to provide supportive atmosphere and for psychiatrist to assess clinical status 4. P-CM- as 3 but with pill placebo | 2. HRSD mean endpoint scores 3. Leaving the study early 4. HRSD>7 5. BDI > 9 | condition, except for CM groups which were carried out double blind by same therapists. 28 therapists (10 psychologists, 18 psychiatrists) all trained in pilot stage of project | |
| Frank 1990 (US) | Allocation: random (patients and members of their treatment team blind to medication or placebo) Duration: approximately 20-week acute phase; 17-week continuation phase, then patients randomised to 3-year maintenance phase | Patients in their third or more depression episode, with previous episode no more than 2.5 years before onset of present episode and minimum 10-week remission between two episodes. N = 128, mean age 40.2 (-+ 10.9) Diagnosis: RDC for unipolar depression, HRSD > 14 , Raskin Severity of Depression > 6 . Patients entering the maintenance phase had major depression, though 14.3% of patients entering the first-phase of treatment diagnosed with bipolar disorder | All patients had received acute phase imipramine (150-300mg) and IPT (weekly for 12 weeks, then bi-weekly for 8 weeks, then monthly for additional 4 months; not clear how many sessions in maintenance phase). Entered maintenance trial if HRSD < 8 and Raskin score < 6 for 3 consecutive weeks 1. IPT - following Klerman et al (1984). Goal was to maintain the well-state by improving the quality of social and interpersonal functioning 2. IPT-M + placebo 3. IPT-M + active imipramine 4. Medication clinic + placebo 5. Medication clinic +imipramine | 1. Relapse (HRSD > 14 + Raskin > 6) at end of 3-year maintenance phase 2. Leaving the study early (at end of 3-year maintenance phase) | Therapists were social workers, psychologists or nurse clinicians with Master's or PhD degrees who were trained in IPT by 2 members who developed IPT and a certified IPT trainer. Data extracted for the following comparisons of interventions: 1 vs 3 and 1 vs 4. | B |

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|----------------------|---|--|---|---|---|---|
| Freeman 2002 (UK) | Allocation: random (no details). Duration: 16 sessions over 5 months, plus 5-month follow-up. | Primary care Diagnosis: DSM-IV major depression or depression with comorbid anxiety. N =124 (depressed or depressed with anxiety), mean age 36 (+-11.2), 79 women | 1. IPT (no details) 2. CBT (no details) 3. TAU (GP care, not controlled but GPs instructed not to refer to psychological therapy or counselling; all on ADs) (1 vs 3 extracted for this review; 1 vs 2 in CBT review) | 1. BDI mean scores at endpoint and at 5-month follow-up | 19 therapists (12 CBT and 7 IPT - none did both) 4 clinical psychologists, 5 research psychologists, 3 psychiatrists, 2 nurse therapists, 1 OT, 4 CPNs Data sub-set of larger study including wider range of depressive and anxiety disorders | B |
|----------------------|---|--|---|---|---|---|

80

| | | | | | | |
|------------------------|---|---|--|---|--|---|
| Reynolds 1999 (US) | Allocation: Random (stratified: by single/recurrent episodes of major depression); AD/placebo administered double blind. Patients originally randomised to 2-arm trial, but later addition of 2 further arms - results presented for 4-arm trial, including patients originally randomised to 2 arms. Duration: Acute phase until patients remitted within an 8-week period. Patients who remitted entered into a 16-week continuation phase and followed-up after 2 years; IPT - weekly 50-minute sessions. | Participants who responded to advertisements or letters sent from the investigators to surviving spouses identified in obituaries N = 80, 68 female, mean age = 66.4. Diagnosis: SDAS-L and RDC for major depressive episode | 1. Medication clinic + nortriptyline 2. Medication clinic + placebo 3. IPT + nortriptyline 4. IPT + placebo | 1. Leaving the study early (acute phase) 2. Non-remitters (by end of acute phase; HRSD not <7 for 3 consecutive weeks) 3. Relapse (patients in continuation phase only) 4. Leaving the study early due to side effects (acute phase) | Therapists were experienced clinicians trained to and maintained at research levels of proficiency in IPT, same clinicians also provided the medication clinic | C |
| Reynolds 1999B (US) | Allocation: random (schedule generated by project statistician, individual randomisation stratified by therapist and blocked in units of 4 subjects, patients and therapists blind to AD or placebo assignment) Duration: Initial acute treatment phase - received nortriptyline + weekly IPT to achieve remission, 16-week continuation treatment phase - nortriptyline + fortnightly IPT. Patients showing stable remission then randomised to 1 of 4 3-year maintenance therapy conditions; IPT - monthly 50-minute sessions, medication clinic - monthly 30-minute visits | Older adults in at least their second lifetime episode and previous episode no more than 3 years before present episode. N = 107; age - 69 between 60 & 69 years, 38 > 69 years. Diagnosis: RDC for unipolar major depression, HRSD >16 | 1. Nortriptyline + IPT 2. Nortriptyline + medication clinic 3. IPT + placebo 4. Medication clinic + placebo | 1. Leaving the study early (at end of 3-year maintenance phase - included patients who refused treatment and medical dropouts) 2. Relapse (at end of maintenance phase) | Therapists were experienced clinicians trained to research level of proficiency by 4 of the investigators. Same clinicians also provided medication-clinical management to medication clinic group. Recurrence of major depressive episode based on structured psychiatric interview | A |
| Schulberg 1996 (US) | Allocation: random (no details) Duration: 8 months (IPT: acute phase 4 months (16 weekly sessions), continuation phase 4 months (4 monthly sessions); Antidepressant: acute phase 6 weeks, 6-month continuation phase | Primary care patients presenting at study site waiting rooms in 4 ambulatory health centres.N = 276, 229 female, mean age 38.1. Diagnosis: for entry to acute phase: DSM-III-R for major depression, HRSD > | 1. IPT - Klerman (1984) 2. Nortriptyline + CM (using NIMH manual, Fawcett, 1987) 3. TAU - usual family physician care; 45% prescribed ADs within 2 months of randomisation | 1. HRSD mean scores at endpoint (month 4 data) and after 4 months' continuation treatment (month 8 data) 2. Leaving the study early | Therapists were psychiatrists and clinical psychologists skilled in psychotherapeutic procedures trained in standardised IPT | B |

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|--------------------|--|--|--|---|---|---|
| | | 12; for continuation phase (AD group only): BDI < 20 and judged to be non-responder by independent psychiatrist | | 3. HRSD >7 after 4 months' continuation treatment (month 8 data) | | |
| Weissman 1992 (US) | Allocation: random (double-blind to ADs or placebo). Duration: 6 weeks, weekly 30-50 minute IPT sessions | Outpatients, ambulatory. N = 35, 25 female, mean age 70 (range 60-83 years) Diagnosis: DSM-III major depression | 1. IPT + alprazolam (mean maximum dose 2.2mg) 2. IPT + imipramine (mean maximum dose 97.5mg) 3. IPT + placebo 1 not extracted | 1. Leaving the study early for any reason 2. Leaving the study early due to side effects | IPT was offered for ethical reasons in light of the placebo and to enhance compliance in general. Evaluating the efficacy of IPT as such was not the objective. IPT based on Klerman et al (1979) | B |

Characteristics of excluded studies

| Study | Reason for exclusion |
|-------------------|--|
| DiMascio1979 (US) | > 50% dropout rate (53/96); also, efficacy data not extractable because no SDs |
| Frank1989 (US) | No extractable data |
| Jacobson1977 (US) | Raskin Depression Scale used for depression diagnosis |

| | |
|---------------------|--|
| Klerman1974 | No extractable data |
| Martin2001 (UK) | 4 out of 15 patients in venlafaxine group and 1 out of 13 patients in the IPT group was assigned in a non-randomised manner |
| Mossey1996 | Patients with 'subdysthymia'- a sub-threshold level for major depression or dysthymia. Excluded patients with major depression or dysthymia. |
| Szapocznik1982 (US) | Not an RCT; formal diagnosis of depression not conducted |
| Zeiss1979 | Patients recruited based on Minnesota Multi-phasic Inventory |

Interpersonal therapy - new studies in the guideline update

Comparisons Included in this Clinical Question

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|---|------------------------|---|--|
| IPT + ADs vs Ads BLOM2007 SCHRAMM2007 | IPT vs CBT LUTY2007 | IPT vs CBT vs Clinical management MARSHALL2008 | IPT vs TAU (psychoeducational materials & referrals) SWARTZ2008 |
|---|------------------------|---|--|

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|---|--|--|
| BLOM2007 Study Type: RCT Type of Analysis: Completers Blindness: Blinded assessments Duration (days): Mean 98 Setting: Community mental health clinics and outpatients; Netherlands Notes: RANDOMISATION: no details | n= 193 Age: Mean 40 Sex: 69 males 124 females Diagnosis: 100% Major depression by DSM-IV Exclusions: <18 years old; HAMD score <14; substance misuse; serious medical condition; organic psychiatric disorder; severe suicidality; history of psychotic disorder or schizophrenia; bipolar disorder; current use of psychotropic medication; ongoing psychotherapy Baseline: HRSD: NEF 20.5 (4.8); NEF/IPT 21.9 (4.3); IPT/PLA 21.4 (5.3); IPT 21.6 (4.1) MADRS: NEF 28.3 (6.7); NEF/IPT 31.0 (5.5); IPT/PLA 29.8 (6.3); IPT 29.5 (5.3) | Data Used Leaving study early for any reason Remission on HAM-D MADRS endpoint HAM-D | Group 1 N= 49 Nefazodone - Started at 100mg/d and gradually increased to minimum of 400mg/d or maximum of 600mg/d Interpersonal psychotherapy - 12 sessions Group 2 N= 47 Interpersonal psychotherapy - 12 sessions Placebo Group 3 N= 50 Interpersonal psychotherapy - 12 sessions Group 4 N= 47 Nefazodone - Started at 100mg/d and gradually increased to minimum of 400mg/d or maximum of 600mg/d | Unrestricted grant from Bristol-Myers Squibb and partially supported by the Netherlands Organisation for Scientific Research |
| LUTY2007 | | | | |

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|---|--|--|---|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT (with LOCF)</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 96 Range 56-112</p> <p>Followup: Not reported</p> <p>Setting: recruited participants from out patient clinics, GPs, self-referrals and psychiatric emergency services.</p> <p>Notes: randomisation: computer randomised.</p> <p>Info on Screening Process: n=282 screened, n=105 excluded as did not meet the inclusion criteria (n=46), missed interview (n=13), preferred their antidepressant treatment (n=11) or not interested in therapy used in study (n=35)</p> | <p>n= 177</p> <p>Age: Mean 35</p> <p>Sex: 49 males 128 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by DSM-IV SCID 22% Alcohol dependence by DSM-IV 15% Cannabis dependence by DSM-IV 16% Panic disorder by DSM-IV 24% Social phobia by DSM-IV 45% Any Personality Disorder by SCID-PQ 11% Paranoid Personality Disorder by SCID-PQ 27% Avoidant personality disorder by SCID-PQ 11% Borderline Personality Disorder by SCID-PQ 13% Obsessive Personality disorder by SCID-PQ <p>Exclusions: <18 years old, no DSM-IV primary diagnosis of major depression. Medication free for less than 2 weeks,</p> | <p>Data Used</p> <ul style="list-style-type: none"> Leaving study early for any reason MADRS change BDI-II endpoint HRSD endpoint MADRS endpoint <p>Data Not Used</p> <ul style="list-style-type: none"> Temperament and Character Inventory - Not relevant MSE endpoint - Not relevant SCL-90 endpoint - Not relevant <p>Notes: Scores on relevant scales taken at baseline and 16- week endpoint. Response defined as 60% reduction in score on MADRS,as well as achieving scores <7 on the HRSD and 10 on the BDI-II. JOYCE2007: Reports MADRS improvement</p> | <p>Group 1 N= 91</p> <p>Interpersonal psychotherapy - Participant booked to see therapist on an approximately weekly basis, for 50 minute sessions for up to 16 weeks. The minimum number of sessions allowed to satisfy the research criteria was 8 and the maximum 19.</p> <p>Group 2 N= 86</p> <p>CBT - Same schedule and time allotment as within the IPT intervention.</p> | <p>Funded by grants from the Health Research Council of New Zealand.</p> |
|---|--|--|---|--|

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| | <p>history of mania, schizophrenia, major physical illness that could interfere with treatment or assessment, current alcohol/drug dependence of moderate or greater severity, severe antisocial personality disorder or if participant had failed to respond to one of the two interventions within the last year.</p> <p>Notes: Severe depression also measured and defined as >29 on MADRS.</p> <table border="1"> <thead> <tr> <th>Baseline: MADRS</th><th>HRSD</th><th>BDI-II</th></tr> </thead> <tbody> <tr> <td>IPT 23.3 (6.5)</td><td>16.0 (4.7)</td><td>27.7 (9.4)</td></tr> <tr> <td>CBT 24.4 (6.2)</td><td>16.7 (4.6)</td><td>28.7 (10.4)</td></tr> </tbody> </table> | Baseline: MADRS | HRSD | BDI-II | IPT 23.3 (6.5) | 16.0 (4.7) | 27.7 (9.4) | CBT 24.4 (6.2) | 16.7 (4.6) | 28.7 (10.4) | | | |
|---------------------|--|--|--|---|----------------|------------|------------|----------------|------------|-------------|--|--|--|
| Baseline: MADRS | HRSD | BDI-II | | | | | | | | | | | |
| IPT 23.3 (6.5) | 16.0 (4.7) | 27.7 (9.4) | | | | | | | | | | | |
| CBT 24.4 (6.2) | 16.7 (4.6) | 28.7 (10.4) | | | | | | | | | | | |
| MARSHALL2008 | <p>n= 102</p> <p>Age:</p> <p>Sex: 32 males 70 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by DSM-IV SCID 6% Dysthymia by DSM-IV SCID 13% Anxiety disorder by DSM-IV SCID <p>Exclusions: No DSM-IV diagnosis of major depression, scoring <10 on the HRSD, concurrent active medical illness, taking antidepressants within 2 weeks prior to therapy (4 weeks for fluoxetine). Exclusions around other psychiatric history and current psychiatric symptoms are vague.</p> <p>Notes: Additional: A score of 10 or more on the HRSD was required for study entry.</p> <p>Baseline: HRSD: CBT = 17.78 (3.58), IPT = 18.57 (4.06), Pharm = 18.53 (3.58)</p> | <p>Data Used HRSD</p> <p>Data Not Used Self-Criticism assessment - Not relevant Depressive Experiences Questionnaire (DEQ) - Not relevant</p> <p>Notes: Assessments made at baseline and at 16 weeks (endpoint).</p> | <p>Group 1 N= 37 CBT - 16 sessions given weekly (although number of sessions varied based on participant's level of symptomatology).</p> <p>Group 2 N= 35 Interpersonal psychotherapy - 16 sessions given weekly (although number of sessions varied based on participant's level of symptomatology).</p> <p>Group 3 N= 30 Pharmacotherapy + Clinical Management - Prescribed an antidepressant selected at treating psychiatrist's discretion.</p> | Supported by an operating grant from the Ontario Mental Health Foundation (OMHF). | | | | | | | | | |
| SCHRAMM2007 | | | | | | | | | | | | | |

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|--|--|---------------|---------------------|------------------|------------|----------------|-------------|---|--|--|
| <p>Study Type: RCT</p> <p>Type of Analysis: ITT "all who received allocated intervention"</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 35</p> <p>Followup: 1 year</p> <p>Setting: Participants referred to the department for acute psychiatric hospitalisation.</p> <p>Notes: Randomisation: stratified for age, gender, unipolar vs bipolar II disorder, comorbidity on axis I, duration of index episode and number of episodes.</p> <p>Info on Screening Process: n=300 prescreened, n=147 screened for eligibility, n=17 excluded as they didn't meet the inclusion criteria or they refused to participate. N=130 randomised, n=6 not analysed.</p> | <p>n= 124</p> <p>Age: Mean 41</p> <p>Sex: 43 males 81 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by DSM-IV SCID 42% Axis I comorbidity by DSM-IV SCID <p>Exclusions: No DSM-IV diagnosis of major depression, <18 or >65 years old, concurrent diagnosis of bipolar I disorder, primary substance misuse/dependency, other primary axis I disorders, mental disorder because of organic factors, and borderline or antisocial personality disorder, psychotic symptoms, severe cognitive impairment, contraindications to the study medication and being actively suicidal.</p> <p>Notes: Additional score of >15 on the Ham-D-17 required for inclusion in this study.</p> <table border="0" data-bbox="482 600 819 664"> <tr> <td>Baseline: IPT</td> <td>Clinical management</td> </tr> <tr> <td>HAM-D 25.1 (5.1)</td> <td>21.9 (4.1)</td> </tr> <tr> <td>BDI 29.5 (7.9)</td> <td>30.1 (10.2)</td> </tr> </table> | Baseline: IPT | Clinical management | HAM-D 25.1 (5.1) | 21.9 (4.1) | BDI 29.5 (7.9) | 30.1 (10.2) | <p>Data Used</p> <ul style="list-style-type: none"> Response on HAM-D Remission on HAM-D Relapse on HAM-D BDI HAM-D <p>Data Not Used</p> <ul style="list-style-type: none"> Social Adjustment Scale - Not relevant <p>Notes: Scores taken at baseline, week 5 (endpoint), 3 months and 12 months.</p> <p>Response= reduction in symptom severity of 50% or higher on HAM-D.</p> <p>Remission= score of <8 on HAM-D</p> <p>Relapse= score >14 on HAM-D, with psychiatric status rating of >4 for 2 weeks.</p> | <p>Group 1 N= 63</p> <p>IPT + Pharmacotherapy. Mean dose 90.2mg/day - 15 individual sessions (+ 8 group sessions) approximately 50 minutes long, administered 3 times a week over 5 weeks. The average number of sessions attended was 12.8. First-line pharmacotherapy was sertraline, followed by amitriptyline.</p> <p>Group 2 N= 61</p> <p>Clinical Management + Pharmacotherapy. Mean dose 90.2mg/day - Participants received a psychoeducational, supportive and empathic intervention of 20 - 25 minutes, 3 times a week. First-line pharmacotherapy was sertraline, followed by amitriptyline.</p> | <p>Funded by grants from the German Research Society, Bonn, Germany.</p> |
| Baseline: IPT | Clinical management | | | | | | | | | |
| HAM-D 25.1 (5.1) | 21.9 (4.1) | | | | | | | | | |
| BDI 29.5 (7.9) | 30.1 (10.2) | | | | | | | | | |
| SWARTZ2008 | | | | 84 | | | | | | |

| <p>Study Type: RCT</p> <p>Type of Analysis: ITT - 'individuals entering treatment.'</p> <p>Blindness: Single blind</p> <p>Duration (days):</p> <p>Followup: 9 months</p> <p>Notes: Randomisation: no details of procedure.</p> <p>Info on Screening Process: n=72 screened, n=65 randomly assigned. Final screening after randomisation removed n=9, and n=9 dropped out leaving n=47 entering interventions.</p> | <p>n= 47</p> <p>Age: Mean 42 Range 18-65</p> <p>Sex: all females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Major depression by DSM-IV 79% Axis I comorbidity by DSM-IV <p>Exclusions: <18 and > 65 years old, no DSM-IV diagnosis of depression, HAM-D score <15 and not the biological or adoptive mother and custodial parent of a child age 6-18 receiving psychiatric treatment. Further exclusion criteria: not living with a child, at serious risk of child abuse/neglect, substance misuse within preceding 6 months, actively suicidal, suffering from psychotic disorder, unstable medical condition that may affect mood ratings or currently receiving individual psychotherapy (group or family therapy was acceptable).</p> <p>Notes: Additional: Score of >15 on the HAM-D-17 also required for study entry.</p> <table border="1" data-bbox="480 659 797 743"> <thead> <tr> <th>Baseline:</th><th>IPT</th><th>TAU</th></tr> </thead> <tbody> <tr> <td>BDI</td><td>24.5 (8.3)</td><td>27.1 (8.3)</td></tr> <tr> <td>HAM-D-17</td><td>20.7 (4.4)</td><td>22.4 (4.2)</td></tr> </tbody> </table> | Baseline: | IPT | TAU | BDI | 24.5 (8.3) | 27.1 (8.3) | HAM-D-17 | 20.7 (4.4) | 22.4 (4.2) | <p>Data Used</p> <ul style="list-style-type: none"> BDI HAM-D <p>Data Not Used</p> <ul style="list-style-type: none"> Child Behaviour Checklist - Not relevant Columbia Impairment Scale - Not relevant Children's Depressive Inventory - Not relevant CGI-S - Not relevant Beck Anxiety Inventory - Not relevant Global Assessment of Functioning scale - Not relevant <p>Notes: Scores taken at baseline, 3 months and 9 months</p> | <p>Group 1 N= 26</p> <p>Interpersonal psychotherapy - One engagement session, followed by eight sessions. Therapy took place in same clinic at the same time the child is receiving treatment. No details on time scale. N=7 were taking antidepressants at baseline, and continued through the study.</p> <p>Group 2 N= 21</p> <p>TAU - Participants in this group were informed of diagnoses, given psychoeducational materials and told to seek treatment, using GP care. They were also given referrals to mental health clinics and (n=11) recorded receiving antidepressants by 3-month follow-up.</p> | <p>Supported by grants from National Institute of Mental Health.</p> |
|---|---|------------|-----|-----|-----|------------|------------|----------|------------|------------|---|--|--|
| Baseline: | IPT | TAU | | | | | | | | | | | |
| BDI | 24.5 (8.3) | 27.1 (8.3) | | | | | | | | | | | |
| HAM-D-17 | 20.7 (4.4) | 22.4 (4.2) | | | | | | | | | | | |

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|----------------|---|
| BODENMANN2008 | In couples therapy review |
| BOLTON2003 | Control intervention not clear. Non-depressed population have an unclear diagnosis. |
| FRANK2007 | Data not extractable |
| MCBRIDE2006 | No extractable data |
| VAN SCHAIK2007 | Data not extractable |

References of Included Studies

BLOM2007 (Published Data Only)
 Blom, M.B.J., Jonker, K., Dusseldorp, E. et al., (2007) Combination treatment for acute depression is superior only when psychotherapy is added to medication. *Psychotherapy and Psychosomatics*, 76, 289-297.

LUTY2007 (Published Data Only)

Joyce, P.R., McKenzie, J.M., Carter, J.D., et al. (2007) Temperament, character and personality disorders as predictors of response to interpersonal psychotherapy and cognitive-behavioural therapy for depression. *British Journal of Psychiatry*, 190, 503-508.

*Luty, S.E., Carter, J.D., McKenzie, J.M., et al. (2007) Randomised controlled trial of interpersonal psychotherapy and cognitive-behavioural therapy for depression. *British Journal of Psychiatry*, 190, 496-502.

MARSHALL2008 (Published Data Only)

Marshall, M.B., Zuroff, D.C., McBride, C., & Bagby, R.M. (2008) Self-criticism predicts differential response to treatment for major depression. *Journal of Clinical Psychology*, 64 (3), 231-244.

SCHRAMM2007

(Published Data Only)

Schramm, E., Schneider, D., Zobel, I., et al. (2008) Efficacy of interpersonal psychotherapy plus pharmacotherapy in chronically depressed inpatients. *Journal of Affective Disorders*, 109, 65-73. Schramm, E., Van Calker, D., Dykierek, P., Lieb, K., et al. (2007) An intensive treatment program of interpersonal psychotherapy plus pharmacotherapy for depressed inpatients: Acute and long-term results.

American Journal of Psychiatry, 164 (5), 768-777.

85

SWARTZ2008 (Published Data Only)
Swartz, H.A., Frank, E., Zuckoff, A., et al. (2008) Brief interpersonal psychotherapy for depressed mothers whose children are receiving psychiatric treatment. *American Journal of Psychiatry*, 165 (90), 1155-1162.

References of Excluded Studies

- BODENMANN2008** (Published Data Only)
Bodenmann, G., Plancherel, B., Beach, S.R., et al. (2008) Effects of coping-oriented couples therapy on depression: A randomized clinical trial. *Journal of Consulting and Clinical Psychology*, 76, (6), 944-954.
- BOLTON2003** (Published Data Only)
Bolton, P., Bass, J., Neugebauer, R., et al. (2003) Group interpersonal psychotherapy for depression in rural Uganda: A randomized controlled trial. *Journal of the American Medical Association*, 289 (23), 3117-3124.
- FRANK2007** (Published Data Only)
Frank, E., Kupfer, D.J., Buysse, D.J., et al. (2007) Randomized trial of weekly, twice-monthly, and monthly interpersonal psychotherapy as maintenance treatment for women with recurrent depression. *American Journal of Psychiatry*, 164, 761-767.
- MCBRIDE2006**
McBride, C., Atkinson, L., Quilty, L.C., & Bagby, R.M. (2006) Attachment as moderator of treatment outcome in major depression: A randomized control trial of interpersonal psychotherapy versus cognitive behavioural therapy. *Journal of Consulting and Clinical Psychology*, 74 (6), 1041-1054.
- VAN SCHAIK2007**
Van Schaik, D.J.F., van Marwijk, H.W.J., Beekman, A.T.F., de Hann, M., & van Dyck, R. (2007) Interpersonal psychotherapy (IPT) for late-life depression in general practice: Update and satisfaction by patients, therapists and physicians. *BMC Family Practice*, 8, 52.

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Interpersonal therapy - relapse prevention - studies excluded from the guideline update

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|-----------------|--|
| CARREIRA2008 | No relevant data; no relevant outcomes |
| DOMBROVSKI2007B | No extractable data |
| DOMBROVSKI2007C | No relevant outcome measures |

References of Excluded Studies

CARREIRA2008 (Published Data Only)

Carreira, K., Miller, M.D., Frank, E., et al. (2008) A controlled evaluation of monthly maintenance interpersonal psychotherapy in late-life depression with varying levels of cognitive function. International Journal of Geriatric Psychiatry, 23, 1110-1113.

DOMBROVSKI2007B (Published Data Only)

Dombrovski, A.Y., Mulsant, B.H., Houck, P.R., et al. (2007) Residual symptoms and recurrence during maintenance treatment of late-life depression. Journal of Affective Disorders, 103, 77-82.

DOMBROVSKI2007C (Published Data Only)

Dombrovski, A.Y., Lenze, E.J., Dew, M.A., et al. (2007) Maintenance treatment for old-age depression preserves health-related quality of life: A randomized, controlled trial of paroxetine and interpersonal psychotherapy. Journal of the American Geriatric Society, 55, 1325-1332.

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Interpersonal therapy - elderly - maintenance - new studies in the guideline update

Comparisons Included in this Clinical Question

IPT + ADs vs IPT + Placebo

REYNOLDS2006

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|--|--|---|
| REYNOLDS2006 Study Type: RCT Type of Analysis: ITT Blindness: Double blind Duration (days): Mean 730 Followup: Not reported Notes: Randomisation: Stratified according to number of episodes, use of augmented pharmacotherapy, and level of cognitive impairment. Info on Screening Process: n=363, n=153 excluded and n=210 agreed to participate. n=195 started short-term therapy (weekly IPT + ADs) and n=116 responded to treatment and were randomised to maintenance treatment. | n= 116 Age: Mean 77 Sex: 41 males 75 females Diagnosis: 100% Major depression by DSM-IV SCID Exclusions: <70 years of age, had not responded to short-term treatment, and a HRSD score >10. Individuals diagnosed with bipolar disorder or psychotic depression. Notes: Additional: All participants had to score between 0 - 10 on the HRSD for 3 consecutive weeks to show clinical response to short-term treatment. Baseline: HRSD: ADs + IPT = 6.0 (2.9), ADs + Clin Man = 4.9 (2.7), PBO + IPT = 5.5 (2.7), PBO + Clin Man = 5.8 (2.2). | Data Used Recurrence on HRSD Leaving study early for any reason Notes: Recurrence of depression: HRSD score >14 & DSM-IV | Group 1 N= 28 IPT + Paroxetine - IPT was delivered monthly in 45-minute sessions. Group 2 N= 35 Clinical Management + Paroxetine - Clinical management was delivered in monthly 30-minute sessions. Group 3 N= 35 IPT + Placebo - IPT was delivered monthly in 45-minute sessions. Group 4 N= 18 Clinical Management + Placebo - Clinical management was delivered in monthly 30-minute sessions. | GlaxoSmithKline supplied the paroxetine tablets. Supported by grants from the National Institute of Mental Health and the National Center for Minority Health and Health Disparities. |

References of Included Studies

REYNOLDS2006 (Published Data Only)

Reynolds, C.F., Dew, M.A., Pollock, B.G., et al. (2006) Maintenance treatment of major depression in old age. The New England Journal of Medicine, 354, 1130-1138.

Interpersonal therapy - elderly - new studies in the guideline update

Comparisons Included in this Clinical Question

IPT vs TAU (usual GP care)

VAN SCHAIK2006

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|---|--|--|---|
| VAN SCHAIK2006 Study Type: RCT Type of Analysis: ITT Blindness: Single blind Duration (days): Mean 140 Followup: 6 months Setting: conducted in 12 general practices in Amsterdam and surrounding area. Notes: Randomisation: random number table conducted for each site. No further details. Info on Screening Process: n=6719 screened with GDS-15, only n=834 returned and had score relevant from inclusion (>4). N=143 were randomised for interventions as n=691 did not have positive PRIME-MD score, refused or met other exclusion criteria. | n= 143 Age: Mean 68 Range 55-82 Sex: 44 males 99 females Diagnosis: 100% Depression by PRIME-MD Exclusions: <55 years old, scoring <5 of the GDS-15, no diagnosis of depressive disorder as measured by the PRIME-MD. Further criteria: Already receiving treatment for depression, non-Dutch speaking, severe cognitive impairment (measured by the Mini-Mental State Examination as a score of <18). Notes: Additional: a score of >4 on the Geriatric Depression Scale (GDS-15) is also required for study entry. Baseline: MADRS score: IPT group = 19.4 (7.9), CAU = 19.3 (8.6) | Data Used Response on MADRS Remission on MADRS Change in Diagnosis (PRIME-MD) MADRS change MADRS Data Not Used Short-form Health survey (SF-36) - Not relevant Geriatric Depression Scale - Not relevant Notes: Assessments made at baseline, 2 months and 6 months. Remission = MADRS score of <10 Response = MADRS reduction of 50% | Group 1 N= 69 Interpersonal psychotherapy - 10 sessions to be completed within 5 months, provided by 15 therapists. Once allocated to IPT, GPs were informed not to prescribe any antidepressants or refer the participant to any psychotherapy or counselling. Average of 8 sessions received. Group 2 N= 74 Care as usual - Usual care, GPs were not informed about participants unless they became suicidal. | Funded by The Netherlands Organization for Health Research and Development (ZONmw). |

References of Included Studies

VAN SCHAIK2006 (Published Data Only)

Van Schaik, A., van Marwijk, H., Ader, H., et al. (2006) Interpersonal psychotherapy for elderly patients in primary care. American Journal of Geriatric Psychiatry, 14 (9), 777-786.

Counselling - studies in previous guideline

Characteristics of included studies

| | | | | | |
|---------------|---|------------------|---------------|--|--|
| | | | | | |
| | | | | | |
| and 12 months | Concurrent psychotropic medication: 32% therapy & 24% GP group were taking it at beginning of trial 31% & 40% respectively took it between start of trial & 6-month assessment, 40% & 38% respectively prescribed it between 6- & 12-month assessment | 2. Usual GP care | and 12 months | 3. Leaving the study early (by 6 months) | |

| | | | | | |
|------|--------------------|-------------------------------------|--------------------------|-------------|--|
| Ward | Allocation: random | GP referrals N = 464, mean age 34.8 | 1. Usual GP care (30% in | 1. BDI mean | Published version of HTA by King et al. Counsellors - 90 |
|------|--------------------|-------------------------------------|--------------------------|-------------|--|

| | | | | | |
|--------------|--|--|---|--|---|
| 2000 (UK) | (numbered sealed opaque envelopes, blocked and stratified by severity on BDI. Patients with strong preference could choose treatment or be randomised only between treatment groups (i.e. not GP care), but analysis undertaken for preference group, 3-way randomisation and 2-way randomisation separately). Duration: 6-12 weekly 50-minute sessions - no control over when ended | (12.2), 75% female. Diagnosis: BDI ≥ 14 , 62% depression main diagnosis, others 'no overall psychiatric diagnosis' or 'behavioural difficulties'. | counselling group, 27% of CBT group on ADs) 2. CBT - complied with manualised problem formulation and staged intervention approach (Greenberger and Padesky, 1995a, 1995b) 3. Non-directive counselling - used non-directive approach outlined in a manual developed by authors based on Rogers. 2 used in review of CBT | scores at endpoint and 12 month follow-up 2. Leaving the study early by 4 months and by 12 months | accredited by BAC. CBT therapists were psychologists accredited by BABCP and registered with UK Council for Psychotherapy. Several problems with this trial: a) 27% of CBT group were also prescribed ADs by their GP (despite GPs being asked not to) and data not reported separately; b) no control over when sessions were finished (minimum of 6, but up to 12 on offer if necessary). BDI etc scores taken at baseline, 4 months and 12 months, but only managed to get date of therapy completion from 87% in CBT group; of these, only 80 had finished at 4 months. No other information reported on when sessions finished (presumably all within 12 months); c) although inclusion criteria included BDI ≥ 14 , only 62% had main diagnosis of depression. |
|--------------|--|--|---|--|---|

Characteristics of excluded studies

| Study | Reason for exclusion |
|------------------|---|
| Bellamy2000 (UK) | Participants suffering from 'psychological problems' and not diagnosed as depressed |
| Friedli1997 (UK) | Participants suffering from 'emotional difficulty' and not diagnosed as depressed |

| | |
|--------------------|---|
| Gordon1998 | Not an RCT |
| Hemmings1997 (UK) | Includes participants with diagnoses other than depression |
| Mittelman1995 (US) | Only 40% of participants depressed; also, not randomised |
| Vonk1999 (US) | Participants suffering from 'psychiatric disorder' but not diagnosed as depressed |

91

Counselling - new studies in the guideline update

Comparisons Included in this Clinical Question

| | |
|--------------------|------------------------------|
| Counselling vs CBT | Counselling vs counselling |
| WATSON2003 | GOLDMAN2006 GREENBERG1998 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|--|--|---|--|--|
| GOLDMAN2006 Study Type: RCT Type of Analysis: Completers (at least 8 sessions) Blindness: No mention Duration (days): Setting: US (advertisements) Notes: RANDOMISATION: no details | n= 38 Age: Mean 40 Sex: 14 males 24 females Diagnosis: 100% Major depression by DSM-IV Exclusions: Currently in treatment or on medication for depression; bipolar I, panic disorder; substance dependence; eating disorders; psychotic disorder; two or more schizotypal features; paranoid, borderline or antisocial personality disorders; in need of treatment focusing on other problems; in need of immediate crisis intervention; loss of a significant other in past year; victim of incest or sexual abuse; currently in physically abusive relationship Baseline: BDI: CCT 26.26 (7.35); EFT 26.21 (7.10) | Data Used SCL-90-R BDI endpoint Data Not Used Task-Specific Intervention Adherence Measure - not relevant Truax Accurate Empathy Scale - not relevant BLRI - not relevant Inventory of Interpersonal Problems (64 items) - not relevant Rosenberg Self-Esteem Scale - not relevant | Group 1 N= 19 Client-centred treatment - 9-20 sessions (mean 16.84 [1.74]) Group 2 N= 19 Emotion-focused therapy - 9-20 sessions (mean 17.5 [3.25]) | Funding: Ontario Mental Health Foundation grant and two National Institute of Mental Health grants |
| GREENBERG1998 Study Type: RCT Type of Analysis: Completers (minimum 15 sessions completed) Blindness: No mention Duration (days): Setting: Canada (advertisements) Notes: RANDOMISATION: matched on SCL-90 depression score | n= 34 Age: Mean 40 Sex: 9 males 25 females Diagnosis: 100% Major depression by DSM-III-R Exclusions: GAS score <50; >3 prior episodes of MDD; currently in treatment for depression; severe difficulty with social and occupational functioning; judged better suited for psychopharmacological treatment; victims of incest; attempted suicide; lost significant other in past year; in physically violent relationship; misusing drugs or alcohol; eating disorder; antisocial or borderline personality disorder; bipolar or psychotic disorder Baseline: SCL-90-R depression subscale: CCT 2.45 (0.46); PE 2.72 (0.45) | Data Used SCL-90 endpoint BDI endpoint Data Not Used Truax Accurate Empathy Scale - not relevant BLRI - not relevant Working Alliance Inventory - not relevant Longitudinal Interval Follow-up Evaluation II - not relevant Taget complaints (TCBS) - not relevant Inventory of Interpersonal Problems (64 items) - not relevant Rosenberg Self-Esteem Scale - not relevant | Group 1 N= 17 Client-centred treatment - 15 to 20 sessions Group 2 N= 17 Process-experiential treatment - 15 to 20 sessions | Funding: grant from National Institute of Mental Health |
| WATSON2003 Study Type: RCT Type of Analysis: 'ITT' (at least one session) Blindness: Duration (days): Mean 112 Setting: Outpatient clinic (advertisements); Canada | n= 93 Age: Mean 42 Sex: 31 males 62 females Diagnosis: 100% Major depression by DSM-IV | Data Used SCL-90 endpoint BDI endpoint Data Not Used PF-SOC - not relevant Dysfunctional Attitude Scale - not relevant Rosenberg Self-Esteem Scale - not relevant | Group 1 N= 45 CBT - *ITT n randomised to each arm is unclear 16 sessions Group 2 N= 40 Process-experiential treatment - *ITT n randomised to each arm is unclear | Funding: Grant from Social Sciences and Humanities Research Council of Canada 190 |

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|--|--|--|--|
| | manic-depression, eating disorder, borderline, antisocial or schizotypal; high risk of suicide Baseline: BDI: CBT 25.09 (9.10); PE 24.50 (8.39) | | |
|--|--|--|--|

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|--------------|---|
| WARD2000 | Not all sample was depressed. 62% depression. |

References of Included Studies

- GOLDMAN2006** (Published Data Only)
 Goldman, R.N., Greenberg, L.S. & Angus, L. (2006) The effects of adding emotion-focused interventions to the client-centered relationship conditions in the treatment of depression. *Psychotherapy Research*, 16, 537-549.
- GREENBERG1998** (Published Data Only)
 Greenberg, L.S. (1998) Experiential therapy of depression: differential effects of client-centred relationship conditions and process experiential interventions. *Psychotherapy Research*, 8, 210-224.
- WATSON2003** (Published Data Only)
 Watson, J.C., Gordon, L.B., Stermac, L., Kalogerakos, F., & Steckley, P. (2003) Comparing the effectiveness of process-experiential with cognitive-behavioural psychotherapy in the treatment of depression. *Journal of Consulting and Clinical Psychology*, 71 (4), 773-781.

References of Excluded Studies

- WARD2000** (Published Data Only)
 Ward, E., King, M., Lloyd, M., et al. (2000) Randomised controlled trial of non-directive counselling, cognitive-behaviour therapy, and usual general practitioner care for patients with depression. I: Clinical effectiveness. *British Medical Journal*, 321, 1383-8.

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Psychological interventions in older adults – studies in previous guideline

| Study | Source review |
|-------------------|----------------------|
| Reynolds1999 (US) | IPT |
| Reynolds199B (US) | IPT |
| Weissman1992 (US) | IPT |
| Thompson2001 (US) | CBT |

Short-term psychological treatments – studies in previous guideline

| Study | Source review |
|--------------------|----------------------|
| Bedi2000 (UK) | Counselling |
| Miranda2003 (US) | CBT |
| Mynors-Wallis1995 | Problem solving |
| Mynors-Wallis2000 | Problem solving |
| Scott1997 (UK) | CBT |
| Selmi1990 (US) | CBT |
| Shapiro1994 (Mild) | CBT |
| Shapiro1994 (Mod) | CBT |
| Shapiro1994 (UK) | CBT |
| Simpson2003 (UK) | Counselling |
| Ward20000 (UK) | Counselling |

Short-term psychodynamic psychotherapy - studies in previous guideline

Characteristics of included studies

| Study | Methods | Participants | Interventions | Outcomes | Notes | AC |
|------------------------|--|--|---|--|---|----|
| Burnand 2002 | Allocation: random (no details except stratified by presence of personality disorder, previous episodes, gender) Duration: 10 weeks | Outpatients referred for acute outpatient treatment at a community mental health centre N = 95; 45 female, mean age 36 Diagnosis: DSM-IV MDD and HRSD >= 20 (mean baseline: combination 24.3 (+3.2); AD only 24 (+2.9)) | 1. Psychodynamic psychotherapy + clomipramine (dose as below) 2. Clomipramine 125 mg by day 6 (switched to 20-40mg citalopram in cases of bad side effects n=6) + supportive therapy (individual sessions aimed at providing empathetic listening, guidance, support and facilitation of an alliance by one carefully designated caregiver) | 1. Leaving the study early for any reason 2. HRSD at endpoint (completers only) 3. Non-remitters (HRSD > 7) (from personal communication with authors) | Nursing teams were trained for 6 months in the use of specific manuals - those providing psychotherapy (n=4) had experience in crisis intervention practice under psychodynamic supervisions (>2 years) and received weekly supervisions with a psychoanalyst | B |
| Gallagher-Th94 (US) | Allocation: random (no details) Duration: 16-20 sessions, twice a week for first 4 weeks, then once week for remainder of therapy (c20 weeks) | Outpatients - caregivers recruited through referrals from health care professionals approached by letter. N = 66, 61 female, mean age 62 (+9.7) Diagnosis: RDC definite or probable major depression (n=45), RDC minor depression (n=20) or intermittent depressive disorder (n=1) (mean baseline BDI 19.2 (+)). Cared for elderly relatives. | 1. CT following Beck et al (1979) and Lewinsohn et al (1985) 2. Brief psychodynamic therapy (Mann, 1973) | 1. Still meeting RDC criteria for major/minor/interr- mittent depression at endpoint and at 3-month follow-up 2. Leaving the study early | 13 therapists, each saw at least 1 client. 4 were skilled in both therapies, so treated clients in both conditions. 2 had terminal master's degrees in social work, rest were PhD-level psychologists. All had at least 1 year of supervised experience doing psychotherapy with depressed elderly people. 1 and 2 not extracted: means/SDs presented by short-term or long- term carer, but not possible to discover 'n' used. | B |

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|-------------------------|--|--|---|-------------------------------|--|---|
| McLean 1979 (Can) | Allocation: random (no details) Duration: 10 weeks, weekly 1- hour sessions | Outpatients recruited through a 3-stage screening process: telephone, clinical interview and psychometric evaluation N = 154; out of initial 196 recruited, 141 female, mean age, 39.2 (+10.9) Diagnosis: Feighner et al (1972), MMPI >=25 for men, >=29.5 for women; BDI >=23; Lubin's Depression Adjective Check List >=14 | 1. Short-term psychotherapy - following Marmor (1973, 1975), Wolberg (1967), goals were development of insight through psychodynamic forces that initiated the current depression 2. Behaviour therapy - helped clients to avoid their negative and introspective cognitive habits 3. Amitriptyline started at 75 mg, raised to 150mg, weaned at the rate of 25mg/day 4. Relaxation therapy - goals were to appreciate the relation between muscle | 1. Leaving the study early | 7 female and 7 male therapists - licensed psychologists, physicians, or psychiatrists. Efficacy data not extracted since post-treatment sample included replacers. | B |
|-------------------------|--|--|---|-------------------------------|--|---|

95

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|-------------------|--|--|---|--|---|---|
| | | | tension and depression and to return to his or her level of pre-episode physical functioning by developing a significantly increased ability to relax tension in all muscle groups (data not extracted) | | | |
| Shapiro (Mild) | See Shapiro 1994. | Mild defined as BDI scores 16-20 | | See Shapiro 1994. | Data from mild, moderate and severe cases reported separately. | B |
| Shapiro (Mod) | See Shapiro 1994 | Moderate defined as BDI scores 21-26 | | See Shapiro 1994. | Data from mild, moderate and severe cases reported separately. | |
| Shapiro 1994 (UK) | Allocation: random Duration: 8- &16-week versions of therapies (only 16 week extracted). 1-hour weekly sessions. Follow-up at 45 weeks after pre-screening - for 16-week therapy, equivalent to 15 weeks after end of treatment. | Outpatients, recruited from self-referrers responding to recommendations by occupational health personnel or responding to publicity materials distributed at the workplace or by GPs, or referred directly by GPs or mental health services. N = 117, 61 female, mean age 40.5 (+-9.5) Diagnosis: DSM-III for MDD | 1. CBT - a multimodal method somewhat more behavioural in emphasis than Beck et al, 1979. 2. Psychodynamic-interpersonal psychotherapy - based on Hobson's conversational model | BDI mean scores endpoint, 6-month and 12-month follow-up | Five therapists - UK-trained clinical psychologists, 2 had post-qualification training in PI methods and trained the others. All had at least 2 training cases in each treatment x duration conditions. Only data for 16-week therapy conditions extracted as most comparable with other studies. 25 participants on medication at beginning of study - not clear if still the case at the end. | |

Characteristics of excluded studies

| Study | Reason for exclusion |
|--------------------|---|
| Barkham1996 (UK) | No extractable data |
| Kornblith1983 (US) | Participants not randomised to treatment groups |
| Lipman1976 (US) | Used brief supportive contact therapy; open-ended groups - depressed non-study patients used to maintain size of groups |
| Luborsky1996 (US) | Not an RCT |
| McLean1990 (Can) | No extractable data |
| McLean1992 (Can) | Dropouts replaced, not clear if randomly assigned |
| Solomon1995 (US) | Not an RCT |
| Thompson1987 (US) | (CBT vs psychodynamic) Not clear what N's are used in table reporting outcome measures; dropout data not fully reported |

Short-term psychodynamic psychotherapy - new studies in the guideline update

Comparisons Included in this Clinical Question

| | | | |
|---|---|--|---|
| Psychodynamic Psychotherapy + ADs vs Ads | Psychodynamic Supportive Psychotherapy vs Psychodynamic Supportive Psychotherapy + Ads | Short-Term Psychodynamic Psychotherapy vs Ads | Short-term Psychodynamic Psychotherapy vs Supportive Psychotherapy vs Waitlist control |
| KOOL2003 | DEJONGHE2004 | DEKKER2008 SALMINEN2008 | MAINA2005 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|--|---|---|
| DEJONGHE2004 Study Type: RCT Type of Analysis: ITT (all entering treatment+ LOCF) Blindness: Single blind Duration (days): Mean 182 Setting: two outpatients clinics in Amsterdam, Holland. Notes: Randomisation: stratified by age and gender. Info on Screening Process: n=372 met criteria for depression, n=25 refused to participate, n=139 excluded as they scored <12 or >24 on the HRSD. N=208 randomised, but n=17 refused to participate after randomisation. | n= 191 Age: Range 19-65 Sex: 63 males 128 females Diagnosis: 100% Mild or Moderate major depression by DSM-IV Exclusions: <18 and >65 years old, not DSM-IV diagnosis of mild/moderate major depressive disorder, HRSD score of <12 or >24. Further criteria: psycho-organic disorder, drug misuse, a psychotic or dissociative disorder, considered too unreliable to participate (potential "doctor-shopping"), communicate problems, physical restrictions (holidays/leaving country), if participant was already adequately responding with antidepressants during the depressive episode, if they used psychotropic medication and if the participant wished to become pregnant. Participants were also excluded if they were considered "too ill" or "too suicidal" by the psychiatrist. Notes: Additional criteria: Participants were also required to score between 12-24 on the HRSD. Baseline: HRSD: Psychotherapy= 18.14 (3.37) Combined= 17.99 (3.57). | Data Used HRSD change score Remission on HDRS Leaving study due to side effects Leaving study early for any reason Data Not Used SCL-D - Not relevant CGI-S/I - Not relevant Notes: Assessments made at baseline and week 24. Remission= final HRSD score of 7 or less | Group 1 N= 106 Psychodynamic supportive psychotherapy - Consisted of up to 16 sessions delivered within a 6-month period. Group 2 N= 85 Psychodynamic supportive psychotherapy - Consisted of up to 16 sessions delivered with a 6-month period. Pharmacological therapy - Participants started pharmacological treatment within 2 weeks of trial commencing. All participants started on venlafaxine, if unresponsive then switched to SSRI, TCA or lithium augmentation. Psychiatrist also made 8 follow-up appointments. | Supported by unrestricted educational grant from Wyeth Nederland. |
| DEKKER2008 | | | | |

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|---|---|---|---|---|
| <p>Study Type: RCT</p> <p>Type of Analysis: Completer</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 56</p> <p>Followup: Not reported</p> <p>Setting: Consecutive patients newly registered at two outpatient clinics in Amsterdam.</p> <p>Notes: Randomisation: no details of procedure.</p> <p>Info on Screening Process: of the n=204 suitable for this study, n=63 refused randomisation as wanted to choose their own treatment. Of those randomised (n=141), n=11 immediately left the Psychotherapy group, & n=19 left the Pharmacotherapy group. These were not included in analysis</p> | <p>n= 103</p> <p>Age: Range 20-65</p> <p>Sex: 27 males 76 females</p> <p>Diagnosis:</p> <p>100% Moderate depressive episode by CIDI</p> <p>Exclusions: <18 and >65 years old, no DSM-IV diagnosis of depressive episode, HAM-D baseline score of <14 and >26. Further exclusion criteria: drug misuse, psychotic symptoms, communication problems affecting the trial, contraindication for antidepressants, using psychotropic medication other than prescribed in the pharmacotherapy protocol and pregnancy.</p> <p>Notes: Additional diagnosis: baseline HAM-D score between 14 and 26.</p> <p>Baseline: HAM-D score (per protocol sample): Psychotherapy = 20.4 (3.8); Pharmacotherapy = 19.8 (3.7).</p> | <p>Data Used</p> <p>Leaving study early for any reason HAM-D</p> <p>Data Not Used</p> <p>CGI-S/I - Not relevant SCL-90-R (depression) - Not relevant</p> <p>Notes: Scores taken at baseline and at 8 weeks.</p> | <p>Group 1 N= 59</p> <p>Psychodynamic Psychotherapy - Short-term psychodynamic supportive psychotherapy, 16 sessions, weekly for first 8 weeks, then given biweekly thereafter.</p> <p>Group 2 N= 44</p> <p>Pharmacological therapy - Venlafaxine. Starting dose of 75mg/day, increasing a maximum of 225mg/day. Clinical management also provided, 4 appointments biweekly, maximum duration of each was 20 minutes.</p> | <p>Supported by an unrestricted educational grant from Wyeth Nederland.</p> |
| KOOL2003 | | | | 97 |

| | | | | |
|--|---|--|---|---|
| <p>Study Type: RCT</p> <p>Type of Analysis: 'ITT' all participants starting treatment (LOCF)</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 168</p> <p>Setting: Outpatient clinic of Mentrum Mental Health Organisation, Amsterdam</p> <p>Notes: Randomisation: 4 blocks were formed, defined by sex and age.</p> <p>Info on Screening Process: n=525 were diagnosed with depression, but were not included in the study as 6% were under 18, 16% had a HAM-D-17 score <14, 6% refused to participate and 40% did not meet the inclusion criteria. N=167 randomised, n=38 refused proposed treatment.</p> | <p>n= 128</p> <p>Age: Mean 34 Range 20-60</p> <p>Sex: 49 males 79 females</p> <p>Diagnosis:</p> <p>100% Major depression by DSM-III-R</p> <p>Exclusions: <18 and >60 years old, no DSM-II-R diagnosis of major depression, HAM-D-17 score <14. Further criteria included: considered 'too ill' or 'too suicidal' to participate, presentation of drug misuse or a psycho-organic, psychotic or dissociative disorder, and the participant not considered reliable enough to participate in the clinical trial (risk of "shopping" for other therapies was high).</p> <p>Notes: Additional: a score of at least 14 on the HAM-D-17 was also required.</p> <p>Baseline: HAM-D-17: a) with personality disorder; Pharm = 20.75 (4.31), Combined = 20.12 (4.97) b) without personality disorder; Pharm = 21.20 (5.64), Combined = 19.70 (4.80)</p> | <p>Data Used</p> <p>HAM-D</p> <p>Remission on HAM-D</p> <p>Data Not Used</p> <p>Quality of Life Depression Scale - Not relevant</p> <p>SCL-90-R (depression) - Not relevant</p> <p>CGI-S/I - Not relevant</p> <p>Notes: Scores taken at baseline and endpoint (week 24 mean). Remission = HAM-D-17 end score of 7 or less.</p> | <p>Group 1 N= 57</p> <p>Pharmacological therapy - Intention was to continue medication for 6 months. Initially, participants were given fluoxetine 20mg/day, but this was switched to amitriptyline 100mg/day rising to 150mg/day or moclobemide 300mg/day in case of intolerance to fluoxetine</p> <p>Group 2 N= 72</p> <p>Pharmacological therapy - Intention was to continue medication for 6 months. Initially, participants were given fluoxetine 20mg/day, but this was switched to amitriptyline 100mg/day rising to 150mg/day or moclobemide 300mg/day in case of intolerance to fluoxetine</p> <p>Psychodynamic supportive psychotherapy - 16 sessions of 45 minutes. The first 8 were weekly, the second 8 were biweekly. This started within two weeks of pharmacotherapy.</p> | <p>Supported by an unrestricted educational grant from Eli Lilly Nederland.</p> |
| <p>MAINA2005</p> <p>Study Type: RCT</p> <p>Type of Analysis: ITT (no participants dropped-out)</p> <p>Blindness: Single blind</p> <p>Duration (days): Mean 161 Range 105-210</p> <p>Followup: 6 months</p> <p>Setting: Participants were recruited from the outpatient waiting list for BDT at the department of Neuroscience, University of Turin, Italy.</p> <p>Notes: Randomisation: Participants matched by diagnosis and level of education and randomised in three blocks of 10 subjects.</p> <p>Info on Screening Process: n=93 were screened, n=58 considered as they met inclusion criteria. N=3 refused consent and n=25 removed from study as they could not be matched.</p> | <p>n= 30</p> <p>Age: Mean 37 Range 18-60</p> <p>Sex: 11 males 19 females</p> <p>Diagnosis:</p> <p>100% Minor depression or dysthymia by DSM-IV SCID</p> <p>Exclusions: <18 and >60 years old, no main diagnosis of dysthymia or minor depressive disorder according to the DSM-IV SCID, evidence of mental retardation, lifetime history or organic mental disorders, psychotic disorders, bipolar disorders or substance misuse, severe axis II psychopathology, current suicide ideation, current pharmacological treatment, evidence of severe or unstable or active neurological or physical diseases and having been on waiting list for no longer than 1 month. Further exclusion criteria: HAM-D score <8 and >15, CGI-S score <3.</p> <p>Notes: Additional: a score of between 8-15 on the HAM-D and a score of >2 on the CGI-S were also required for study inclusion.</p> <p>Baseline: BDT BSP WL HAM-D: 12.6 (2.7) 11.5 (2.7) 11.8 (2.3)</p> | <p>Data Used</p> <p>HAM-D</p> <p>Data Not Used</p> <p>HAM-A (anxiety) - Not relevant</p> <p>CGI-S/I - Not relevant</p> <p>Notes: Scores taken at baseline, endpoint and 6 months.</p> | <p>Group 1 N= 10</p> <p>Brief Dynamic Therapy - brief form of psychotherapy. Sessions were weekly, lasting 45 minutes, individually administered. The number of sessions ranged from 15-30, the mean was 19.6.</p> <p>Group 2 N= 10</p> <p>Brief Supportive Psychotherapy - Sessions were weekly, lasting 45 minutes, individually administered. The number of sessions ranged from 20-30, the mean was 18.6.</p> <p>Group 3 N= 10</p> <p>Wait list - Contacted weekly by telephone in order to prevent their disappearance.</p> | <p>No details on funding.</p> |
| <p>SALMINEN2008</p> | | | | |

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| <p>Study Type: RCT</p> <p>Type of Analysis: ITT</p> <p>Blindness: No mention</p> <p>Duration (days): Mean 112</p> <p>Followup: 4 months</p> <p>Setting: Recruited participants through 5 occupational health services. Carried out in psychiatric clinics in Finland.</p> <p>Notes: Randomisation: no details of procedure</p> <p>Info on Screening Process: n=85 screened, n=34 failed to meet the inclusion criteria.</p> | <p>n= 51</p> <p>Age: Mean 42 Range 20-60</p> <p>Sex: 16 males 35 females</p> <p>Diagnosis:</p> <ul style="list-style-type: none"> 100% Mild or Moderate major depression by DSM-IV SCID <p>Exclusions: No DSM-IV diagnosis of a mild to moderate depressive episode, HDRS score <15, <20 and >60 years old, taken part in psychotherapeutic or psychopharmacological treatment in preceding 4 months, DSM-VI axis I or II comorbidity, severe somatic illness, contraindication to fluoxetine treatment.</p> | <p>Data Used</p> <ul style="list-style-type: none"> Remission measured by DSM-IV Remission on HDRS Leaving study due to side effects Leaving study early for any reason BDI (21 item) HDRS (17 item) <p>Data Not Used</p> <ul style="list-style-type: none"> SOFAS - Not relevant | <p>Group 1 N= 25</p> <p>Pharmacological therapy - Fluoxetine for 16 weeks. Initial dose was 20mg/day, maximum increased up to 40mg/day if no response by weeks 3-4. Medication supervised by GP, met patient once or twice a month. No details of mean dose.</p> <p>Group 2 N= 26</p> <p>Psychodynamic Psychotherapy - consisted of 16 weekly sessions.</p> | <p>Financially supported by the Social Insurance Institution of Finland, and the Signe and Ane Gyllenberg Foundation, Helsinki.</p> <p>98</p> |
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| | HDRS to be included in this study Baseline: HDRS BDI FLU 18.9 (3.4) 24.8 (7.5) PSY 18.3 (3.1) 22.8 (5.5) | Notes: Scores taken at baseline and 4 months. Remission on HDRS= scoring <8. | | |
|--|--|---|--|--|

Characteristics of Excluded Studies

| Reference ID | Reason for Exclusion |
|---------------|---|
| BARKMAN1999 | Dropouts were replaced |
| BOND2006 | Not an RCT |
| HOGLEND2008 | Less than 50% had formal diagnosis of depression. |
| KNEKT2008 | Not all participants met diagnosis for depression |
| PIPER1998 | No relevant comparisons, not all sample depressed |
| SVARTBERG2004 | Less than 50% have formal diagnosis of depression |
| THYME2007A | No relevant comparisons |

References of Included Studies

DEJONGHE2004 (Published Data Only)

De Jonghe, F., Hendriksen, M., van Aalst, G., et al. (2004) Psychotherapy alone and combined with pharmacotherapy in the treatment of depression. *British Journal of Psychiatry*, 185, 37-45.

DEKKER2008 (Published Data Only)

Dekker, J.J.M., Koelen, J.A., Van, H.L., et al. (2008) Speed of action: The relative efficacy of short psychodynamic supportive psychotherapy and pharmacotherapy in the first 8 weeks of a treatment algorithm for depression. *Journal of Affective Disorders*, 109, 183-188.

KOOL2003 (Published Data Only)

Kool, S., Dekker, J., Duijsens, I.J., de Jonghe, F., & Puite, B. (2003) Efficacy of combined therapy and pharmacotherapy for depressed patients with or without personality disorders. *Harvard Review of Psychiatry*, 11(3), 133-141.

MAINA2005 (Published Data Only)

Mania, G., Forner, F., Boggetto, F. (2005) Randomized controlled trial comparing brief dynamic and supportive therapy with waiting list condition in minor depressive disorders. *Psychotherapy and Psychosomatics*, 74, 43-50.

SALMINEN2008 (Published Data Only)

Salminen, J.K., Karlsson, H., Hietala, J., et al. (2008) Short-term psychodynamic psychotherapy and fluoxetine in major depressive disorder: A randomized comparative study. *Psychotherapy and Psychosomatics*, 77, 351-357.

References of Excluded Studies

BARKMAN1999 (Published Data Only)

Barkman, M., Shapiro, D.A., Hardy, G.E., & Rees, A. (1999) Psychotherapy in two-plus-one sessions: Outcomes of a randomized controlled trial of cognitive-behavioural and psychodynamic-interpersonal therapy for subsyndromal depression. *Journal of Consulting and Clinical Psychology*, 67 (2), 201-211.

BOND2006

Bond, M. (2006) Psychodynamic psychotherapy in the treatment of mood disorders. *Current Opinion in Psychiatry*, 19, 40-43.

HOGLEND2008

Hoglend, P., Bogwald, K.P., Amlo, S., et al. (2008) Transference interpretations in dynamic psychotherapy: Do they really yield sustained effects? American Journal of Psychiatry, 165 (6), 763-771.

KNEKT2008

Knekt, P., Lindfors, O., Harkanen, T. et al. (2008) Randomized trial on the effectiveness of long- and short-term psychodynamic psychotherapy and solution-focused therapy on psychiatric symptoms during a 3-year follow-up. Psychological Medicine, 38, 689-703.

PIPER1998

(Published Data Only)

Piper, W.E., Joyce, A.S., McCallum, M., & Azim, H.F. (1998) Interpretive and supportive forms of psychotherapy and patient personality variables. Journal Consulting and Clinical Psychology, 66 (3), 558-567.

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204

SVARTBERG2004

Svartberg, M., Stiles, T.C., & Seltzer, M.H. (2004) Randomized, controlled trial of the effectiveness of short-term dynamic psychotherapy and cognitive therapy for cluster C personality disorders. American Journal of Psychiatry, 161 (5), 810-817.

THYME2007A

Thyme, K.E., Sundin, E.C., Stahlberg, G., Lindstrom, B., Eklof, H., & Wiberg, B. (2007) The outcome of short-term psychodynamic art therapy compared to short-term psychodynamic verbal therapy for depressed women. Psychoanalytic Psychotherapy, 21 (3), 250-264.

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100

206

Short-term psychodynamic psychotherapy - relapse prevention - new studies in the guideline update

Comparisons Included in this Clinical Question

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| Psychodynamic Psychotherapy + ADs vs ADs | |
| MAINA2008 | |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|--|--|--|------------|
| MAINA2008 Study Type: RCT Type of Analysis: ITT Blindness: Single blind Duration (days): Mean 180 Followup: 48 month Setting: Mood and anxiety disorders unit, Department of Neuroscience, University of Turin (Italy) Notes: Randomisation: coloured balls withdrawn from a bag. Info on Screening Process: n=171 met inclusion criteria, n=20 excluded had no focal problem or precipitant life event, n=3 refused consent. N=148 entered acute phase, n=92 remitted and entered continuation treatment. | n= 92 Age: Mean 36 Range 18-65 Sex: 36 males 56 females Diagnosis: 100% Remission from major depression by DSM-IV SCID Exclusions: No primary diagnosis of MDD, single episode by the DSM-IV, baseline HAM-D >14, non-presence of a focal problem and/or of a recent precipitant life event, <18 and >65 years of age. Further criteria: evidence of mental retardation, lifetime history of organic mental disorders, severe axis II psychopathology, concomitant severe or unstable or active neurological or physical distress, substance and drug misuse, any contraindication for an antidepressant prescribed in the pharmacotherapy protocol, pregnancy or risk of pregnancy during the medication treatment phase of the study and suicidal risk. Notes: Additional: score of <15 on the HAM-D also required. Baseline: HAM-D: PP+ADs= 5.5 (1.2) ADs= 5.6 (1.3) | Data Used Recurrence (on HAM-D) HAM-D Data Not Used GAF-self - Not relevant CGI-S/I - Not relevant Notes: Assessments were taken at endpoint, 24 months and 48 months after treatment end. Recurrence: HAM-D score >12 for 2 consecutive visits | Group 1 N= 41 Brief dynamic therapy + Pharmacotherapy. Mean dose 34mg/day - Individual sessions were weekly, lasting 45 minutes. Number of sessions ranged from 15-30 per participant. Pharmacotherapy protocol was same as that for the pharmacotherapy alone intervention. Group 2 N= 51 Pharmacological therapy. Mean dose 34mg/day - Paroxetine or Citalopram provided at a minimum dose of 20mg/day, rising to 60mg/day. Clinical management was also provided by a psychiatrist. | No details |

References of Included Studies

- MAINA2008** (Unpublished Data Only)
Maina, G., Rosso, G., & Bogetto, F. (2008) Brief dynamic therapy combined with pharmacotherapy in the treatment of major depressive disorder: Long-term results. Journal of Affective Disorders (in press).

101

208

Rational emotive behavioural therapy - new studies in the guideline update

Comparisons Included in this Clinical Question

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|---|
| Rational Emotive Behavioural therapy vs ADs vs Cognitive therapy |
| DAVID2008 |

Characteristics of Included Studies

| Methods | Participants | Outcomes | Interventions | Notes |
|---|---|--|--|--|
| DAVID2008 Study Type: RCT Type of Analysis: 'ITT' (but not at follow-up) Blindness: Single blind Duration (days): Mean 98 Followup: 6 months Notes: Randomisation: stratified for previous episodes of depression, presence of dysthymia, sex and marital status. Info on Screening Process: n=323 assessed for eligibility, n=153 excluded (n=133 did not meet the inclusion criteria, and n=20 refused to participate). | n= 170 Age: Mean 37 Sex: 57 males 113 females Diagnosis: 100% Major depression by DSM-IV SCID 15% Dysthymia by DSM-IV SCID Exclusions: No DSM-IV diagnosis of major depression, psychiatric disorders (i.e. bipolar, or psychotic subtypes of depression, panic disorder, current substance misuse, past or present schizophrenia or schizopreniform disorder, organic brain syndrome, or mental retardation). Additionally excluded individuals in some concurrent psychotherapy, receiving psychotic medication, or needed to be hospitalised due to imminent suicide potential or psychosis. Notes: BDI-II score >19 and HRSD-17 score >13 also required. Baseline: CBT REBT Pharmacotherapy HRSD 22.9 (7.02) 23.1 (7.6) 21.4 (8.03) BDI 29.9 (9.47) 32.1 (11) 30.6 (11.3) | Data Used BDI-II HRSD Leaving study due to side effects Leaving study early for any reason Notes: Scores taken at baseline, 7 weeks, endpoint and 6-month follow-up. | Group 1 N= 57 REBT - maximum of 20 sessions over 14 weeks. Sessions were 50 minutes long, held on an individual basis. Group 2 N= 56 CBT - same schedule and session frequency as REBT intervention. Group 3 N= 57 Pharmacological therapy. Mean dose 50mg/day - Fluoxetine. Starting dose was 10mg/day raising to a maximum 60-80mg/day. Dosage reduced to 20mg/day in weeks 12-14 in 53% of participants who fitted improvement criteria (HRSD<12). Pharmacotherapy sessions lasted around 30 minutes. | Funding support was provided by the Albert Ellis Institute, the National Council for Research and the Romanian Center for Cognitive and Behavioural Psychotherapies. |

References of Included Studies

DAVID2008

(Published Data Only)

Sava, F.A., Yates, B.T., Lupu, V., Szentagotai, A., & David, D. (2009) Cost-effectiveness and cost-utility of cognitive therapy, rational emotive behavioural therapy, and fluoxetine (Prozac) in treating depression: A randomized clinical trial. *Journal of Clinical Psychology*, 65, 36-52.

*David, D., Szentagoti, A., Lupu, V., & Cosman, D. (2008) Rational emotive behaviour therapy, cognitive therapy, and medication in the treatment of major depressive disorder: A randomised clinical trial, posttreatment outcomes, and six-month follow-up. *Journal of Clinical Psychology*, 64, 728-746.

102

210

Studies included in previous guideline and excluded in the guideline update

| Study ID | Previous guideline review | Reason for exclusion |
|-----------------|----------------------------------|--|
| BOWMAN1995 | Self-help | Dropouts were replaced |
| WOLLERSHEIM1991 | Self-help | n<10 in each arm |
| DOWRICK2000 | Problem-solving therapy | <80% met criteria for diagnosis of depression |
| LEFF2000 | Couples therapy | >50% dropout in one study arm |
| WARD2000 | Counselling | <80% met criteria for diagnosis of depression; trial not completely randomised |

103

212