Appendix K: Clinical evidence – examples of study characteristics data extraction and methodology checklist

A Microsoft Excel-based data extraction tool, developed by National Collaborating Centre for Mental Health staff, was adapted for use in the current context to extract evidence from randomised controlled trials.

The following screen grabs provide an example of the study characteristics extracted for each study and the methodology checklist. Further information was extracted about funding, publication status, comparisons and study results (not shown).

Review Manager 5.1 was used to extract data for the review of case identification instruments. Microsoft Word-based forms were used to extract evidence about access to services and the experience of care.

1 Example of study characteristics data extraction

Study_ID	Group2	Population	Year	Country	Recruit_Loc	Recruit_Q	N_Rand	Diagnosis	Target_behaviour	Diagnosis_BehaviourQ	IQ_Cutoff	Age_Min	Age_Max	Autism_Exc	OtherIn/Exclusions_Q
Akhondzadeh 2008	0.1 Placebo	Children and young people	2008	Iran	Outpatient Services	Children's outpatient clinic of Roozbeh Hospital.	40	Autism	Challenging behaviour (not specified)	i) DSM IV-TR autism; ii) Patients presented with a	N/R	3	11	Selected for	i) Children were excluded if they had
Aman 2002	0.1 Placebo	Children and young people	2002	USA	N/R	N/A	58	Learning Disabilities	Challenging behaviour (not specified)	i) An axis II diagnosis of subaverage IQ; ii) DSM-	70	5	12	N/R	Inclusion: i) Vineland Adaptive Behavior Scale
Amminger 2007	0.1 Placebo	Children and young people	2007	Austria	Outpatient Services	Study participants were recruited from children and adolescents	13	Autism	Irritability	i) DSM-IV autism; ii) severe tantrums,	N/R	5	17	Selected for	i) Inclusion: weight ≥ 15kg; mental age of ≥ 18
Amore 2011	4.3 Antipsychotics: Risperidone	Adults	2011	Italy	Inpatient Services	Participants in the study were consecutive patients attending a	62	Learning Disabilities	Challenging behaviour (aggression)	i) severe mental retardation (DSM-IV TR)	N/A	N/R	N/R	N/R	i) all patients were receiving a FGAs for a
Bilgin 2009	0.2 Wait list	Family carers of children and young	2009	Turkey	Education Services	The mothers were informed about the study by the	90	Learning Disabilities	None	i) children with intellectual disability; ii) (not	N/R	N/R	N/R	N/R	i) (excluded mothers who were not able to
Chan 2005	0.5 Attention/Monitoring	Mixed	2005	Hong Kong	Inpatient Services	Participants were recruited from a developmental disability unit in	89	Learning Disabilities	Challenging behaviour (not specified)	i) Diagnosed with mental retardation according to	N/R	11	71	N/R	i) Exclusion criteria: History of epilepsy
Craft 1987	0.1 Placebo	Adults	1987	UK	Inpatient Services	Five centres participated in the trial, contributing a total of 42	42	Learning Disabilities	Challenging behaviour (aggression)	i) mentally handicapped in-patients; ii) exhibiting	N/A	N/R	N/R	N/R	i) Patients were excluded from the trial if they
Davis 1991	0.3 Treatment as usual	Family carers of children and young	1991	UK	Community referral (e.g.	Tower Hamlet's Child Development Team in East	80	Learning Disabilities	None	i) families of children with intellectual or multiple	N/R	N/R	N/R	N/R	N/A
Ferraioli 2013	5.1 Parent Training	Family carers of children and young	2013	USA	Mixed	Participants were recruited through the Outreach Division of	21	Autism	None	i) The participants' children represented	N/R	N/R	N/R	Selected for	Parents were required to be the primary
Gagiano 2005	0.1 Placebo	Adults	2005	Worldwide (Multiple)	Unclear	N/R	77	Learning Disabilities	Challenging behaviour (not specified)	i) Axis II diagnosis of borderline intellectual	35 to 84	18	65	N/R	i) Patients were healthy, according to results of a
Gammon 1991	0.4 No treatment	Family carers of children and young	1991	USA	Education services	Parents were recruited for the study using fliers	42	Developmental Disabilities	None	i) Child with specific developmental or other	N/R	N/R	N/R	N/R	i) The parents must have known about their
Gencoz 1997	0.3 Treatment as usual	Children and young people	1997	Turkey	Education services	Children were chosen from a state school for persons with	26	Learning Disabilities	Challenging behaviour (not specified)	i) persons with trainable mental retardation; ii)	N/R	N/R	N/R	N/R	i) Must be able to pass 50% of the Gross Motor
Ghanizadeh 2013	4.3 Antipsychotics: Risperidone	Children and young people	2013	Iran	Outpatient Services	Children were recruited from the child psychiatry outpatient clinic	59	Autism	Irritability	i) DSM-IV autism spectrum disorders; ii)	N/R	4	18	Selected for	i) Excluded children with a history of medically
Greaves 1997	0.5 Attention/Monitoring	Family carers of children and young	1997	Australia	Education services	The sample of 54 mothers was attending an early intervention	54	Down Syndrome	None	i) Pre-school children with Down syndrome ii)	N/R	N/R	N/R	N/R	N/A

STUDY	RANDOMISATION			PARTICIPANT DEMOGRAPHICS										
Study_ID	Num_Group	Unit_Rand	N_Cluster	Age (yrs)	Sex (% F)	Race (% Whit	IQ	Diagnosis	ID_DisabilityLevel_(	Baseline_CB_Q	CurrMed	Med_Q	Autism	OtherDemo_Q
Akhondzadeh 2008	2	Individual	N/A	6.80	25.00	N/R	N/R	Autism	N/R	N/R	N/R	N/A	100.00	(100% autism).
Aman 2002	2	Individual	N/A	8.74	20.67	56.90	57	Learning Disabilities	Mild mental retardation = 65.56%;	(Nisonger Child Behavior Rating Form	N/R	Use of consistent doses of	N/R	DSM-IV axis I diagnosis:
Amminger 2007	2	Individual	N/A	11.24	0.00	N/R	N/R	Autism	N/R	(ABC-I at baseline = 28.09)	N/R	N/A	100.00	(100% autism).
Amore 2011	2	Individual	N/A	48.00	27.40	N/R	N/R	Learning Disabilities	(100% Severe ID)	N/R	100.00	At the beginning of the study, all	N/R	All had a Clinical Global Impression-
Bilgin 2009	2	Individual	N/A	34.03	100.00	N/R	N/R	Learning Disabilities	(100% intellectual disability)	N/R	N/R	N/R	N/R	N/R
Chan 2005	2	Individual	N/A	N/R	59.52	N/R	N/R	Learning Disabilities	Mild mental retardation = 49.44%;	i) (Checklist of Challenging Behaviour	100.00	Most participants had a diagnosis of	N/R	i) Schizophrenia/psyc
Craft 1987	2	Individual	N/A	32.76	30.95	N/R	N/R	Learning Disabilities	(Mild mental handicap = 9.52%; moderate	(Aggressive = 52.38%; self-	N/R	Other medication currently being	N/R	N/A
Davis 1991	2	Individual	N/A	32.63	100.00	65.00	N/R	Learning Disabilities	General quotient= 59.82 (equivilent to	N/R	N/R	N/R	N/R	N/R
Ferraioli 2013	2	Individual	N/A	N/R	66.60	33.00	N/R	Autism	The participants' children represented	N/R	N/R	N/A	100.00	Socioeconomic background was
Gagiano 2005	2	Individual	N/A	29.77	38.96	N/R	56	Learning Disabilities	(Borderline intellectual functioning =	(Mean ABC-total= 49.65)	5.19	N/A	N/R	(ASPD = 5.18%; Conduct disorder
Gammon 1991	2	Individual	N/A	38.43	100.00	N/R	N/R	Developmental Disabilities	(i. Proportion of each diagnosis N/R but	N/R	N/R	N/R	N/R	N/R
Gencoz 1997	2	Individual	N/A	12.08	N/R	N/R	N/R	Learning Disabilities	trainable mentally retarded children	Adaptive Behaviour Scale (ABS)-	N/R	N/R	N/R	N/R
Ghanizadeh 2013	2	Individual	N/A	9.55	18.63	N/R	N/R	Autism	N/R	N/R	N/R	No marked change in dose of	93.50	Mean weight= 32.05;. Mean
Greaves 1997	3	Individual	N/A	N/R	100.00	N/R	N/R	Down Syndrome	(100% Down Syndrome)	N/R	N/R	N/R	N/R	N/R

Challenging behaviour and learning disabilities

2 Example of methodology checklists

STUDY	SEQUENCE GENERATION			ALLOCATION CONCEALMENT		BLINDING (performance and detection bias)					MISSING OUTCOME DATA		
Study_ID	RandMethod	Quotation	ROB	Quotation	ROB	Participants	Providers	ROB	Outcome Assessors	ROB	Mthd_Analy	Quotation	ROB
Akhondzadeh 2008	Computer/Online	Patients were randomized to receive piracetam or	Low	The assignments were kept in sealed, opaque envelopes	Low	Throughout the study, the person who administered	Throughout the study, the person who administered	Low	Throughout the study, the person who administered	Low	No dropout / Denominator is all	All patients completed the trial and there were no	Low
Aman 2002	Unclear	Participants were randomly assigned to receive	Unclear	N/R	Unclear	Double blind.	Double blind.	Low	Double blind.	Unclear	Last observation carried forward	An intent-to-treat design was used, with the last	Low
Amminger 2007	Unclear	Children were randomly assigned.	Unclear	N/R	Unclear	Double blind (no further detail with regard to who is	Double blind (no further detail with regard to who is	Low	Double blind (unclear if assessor was blind)	Unclear	Available case	(Main analysis is available case and extracted	Low
Amore 2011	Unclear	Randomised to olanzapine and to risperidone.	Unclear	N/R	Unclear	Single-blind (no further info)	Single-blind (no further info)	Unclear	Blind assessment of outcome	Low	No dropout / Denominator is all	(62 randomised and 62 included in analyses)	Low
Bilgin 2009	Computer/Online	Participants were then randomly allocated to the	Low	Allocation was concealed from the recruiting	Low	The intervention group was then asked to attend the	N/R	N/A	self-completion questionnaire (for mothers)	High	No dropout / Denominator is all	(45 randomised to each group & 45 analysed for	Low
Chan 2005	Mechanical, e.g. coin toss	Randomly assigned to experimental and control	Low	N/R	Unclear	N/R	A nurse specialist acted as carer and enabler in the	N/A	i) A research assistant entered the room with the	High	No dropout / Denominator is all	(Table 3 shows same numbers of Ps at pre- and	Low
Craft 1987	Minimisation	Allocation to either the active or placebo group	Low	N/R	Unclear	The pathologist or another doctor at each centre	Double blind (no further detail with regard to who,	Low	Double blind (no further detail with regard to who,	Unclear	No dropout / Denominator is all	No participants were withdrawn from the study.	Low
Davis 1991	Unclear	Consecutive referrals were randomly allocated either to	Unclear	N/R	Unclear	N/A	N/A	N/A	(Primary outcome, Malaise inventory, self report)	High	Unclear	Data on three Bangladeshi families were excluded,	Unclear
Ferraioli 2013	Unclear	Parents were divided into matched pairs based on	Unclear	N/R	Unclear	N/R	For the fall cohort, both groups were led by the	N/A	(self report)	High	Available case	Completer analyses were conducted, considering	High
Gagiano 2005	Other	Patients were randomly allocated in equal numbers	Low	N/R	Unclear	Double-blind.	Double-blind	Low	In the double-blind study, the clinician who scored	Low	Last observation carried forward	Data from all randomized patients who had taken	Low
Gammon 1991	Unclear	Parents meeting the eligibility requirements for	Unclear	N/R	Unclear	The interventions involved parents' active participation	Coping Skills Training Program (CSTP), designed	N/A	(Unblinded Self-report)	High	Unclear	N/R	Unclear
Gencoz 1997	Unclear	subjects were then tested on the Turkish	Unclear	N/R	Unclear	N/R	N/R	N/A	(reported by parents and teachers; blinding not	Unclear	Unclear	(No mention of dropout or missing data)	Unclear
Ghanizadeh 2013	Unclear	Participants were randomly assigned to one of the two	Unclear	N/R	Unclear	Patients were blind to treatment assignment.	The clinician who administered the	High	Both rater and the patients were blind to	Low	Imputation (those receiving some	A second round of statistical analyses using	Low
Greaves 1997	Unclear	The mothers were randomly assigned to one	Unclear	N/R	Unclear	The titles of the seminars in both the REPE and ABA	N/R	N/A	(Unblinded Self-report)	High	Unclear	N/R	Unclear

	A	AU	AV	AW	AX	AY	AZ	BA	BB	BC	BD	BE	BF	BG
1	STUDY			SELECTIVE OUTCOME REPORTING					OTHER BIAS		FUNDING		PUBLICATION TYPE	
2	Study_ID	Registered	Reg_Num	Primary_Outcomes	Secondary_Outcome	Quotation	ROB	Quotation	Stopped_Ear	ROB	Funding_Sour	Pub_Statu	Unpub_D	Unpub_Description
3	Akhondzadeh 2008	No	N/R	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	N/A	Each child was rated at baseline and at week 2,	High	N/A	No	Low	Tehran University of	Published paper(s)	No	N/A
4	Aman 2002	No	(This study was not	LOW- The study protocol is not available but it is clear that the published reports include all expected outcomes,	N/A	(All outcomes reported in the correct format;	Low	(i.Study medication and support was provided by	No	High	Janssen Research	Published paper(s)	No	N/A
6	Amminger 2007	N/R	N/A	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	(All outcomes reported in the correct format)	Unclear	N/A	No	Low	Study medication	Published paper(s)	No	N/A
7	Amore 2011	N/R	N/A	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	(Study reports that outcomes were recorded at	Unclear	Cumulative numbers of episodes of verbal	No	Low	N/R	Published paper(s)	No	N/A
10	Bilgin 2009	N/R	N/R	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	(All outcomes reported in the correct format)	Unclear	N/A	No	Low	Research foundation of	Published paper(s)	No	N/A
15	Chan 2005	N/R	N/A	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	(All outcomes reported in the correct format)	Unclear	N/A	No	Low	Health Care and Promotion Fund	Published paper(s)	No	N/A
17	Craft 1987	N/R	N/A	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	N/A	(mean aggression scores not reported, no SD)	High	i) The administration of additional medication to	No	High	N/R	Published paper(s)	No	N/A
18	Davis 1991	N/R	N/R	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	HIGH- Not all of the study's pre-specified	Although results for all the measures are available, in	High	N/A	No	Low	Mental Health Foundation.	Published paper(s)	No	N/A
21	Ferraioli 2013	No	N/A	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	HIGH- One or more outcomes of interest in the	(One or more outcomes of interest in the review are	High	i) Despite randomization efforts to reduce between-	No	High	Organization for Autism	Published paper(s)	No	N/A
22	Gagiano 2005	N/R	N/A	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	BPI scores (total score and self-injurious behavior,	Unclear	This work was supported by Johnson & Johnson	No	High	Johnson & Johnson	Published paper(s)	No	N/A
23	Gammon 1991	N/R	N/R	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	N/A	(Outcome scores presented as mean ranks)	High	N/A	No	Low	N/R	Published paper(s)	No	N/A
24	Gencoz 1997	N/R	N/A	UNCLEAR -Insufficient information to permit judgement of 'Yes' or 'No'. It is likely that the majority of studies	N/A	(All outcomes reported in the correct format)	Unclear	N/A	No	Low	N/R	Published paper(s)	No	N/A
25	Ghanizadeh 2013	Yes	IRCT201110 233930N15	LOW- The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes	N/A	(All outcomes reported in the correct format)	Low	(Authors associated with the study have received	No	High	Author (MB) is supported by	Published paper(s)	No	N/A
26	Greaves 1997	N/R	N/R	HIGH- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered	N/A	(Outcome scores presented as mean change only; no	Unclear	N/A	No	Low	N/R	Published paper(s)	No	N/A