Appendix O: Clinical evidence – GRADE evidence profiles for all studies

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A.1 Risk markers associated with the development of behaviour that challenges

A.1.1 Auditory impairment

Table O.1: Auditory impairment versus no auditory impairment as a risk factor for challenging behaviour

Quality ass	essment						Summary o	of findings			
Participant s	Risk of bias	Inconsistency	Indirectnes s	Imprecisio n	Publicatio n bias	Overall quality of	Study event	rates (%)	Relative effect	Anticipated effects	absolute
(studies) Follow up						evidence	With no impairmen t	With auditory impairmen t	(95% CI)	Risk with no impairmen t	Risk difference with auditory impairmen t (95% CI)
All aggress	ion (phys	sical, verbal and	d destructive)	(assessed w	ith: Validated	d questionnaire)				
1938 (2 studies)	no seriou s risk of bias	serious ¹	no serious indirectnes s	no serious imprecisio n	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to inconsistency	380/1628 (23.3%)	35/310 (11.3%)	OR 0.97 (0.42 to 2.23)	233 per 1000	5 fewer per 1000 (from 120 fewer to 171 more)
Self-injury (assessed	d with: Validate	d questionnai	re)							
2086 (3 studies)	no seriou s risk of bias	serious ¹	no serious indirectnes s	no serious imprecisio n	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to inconsistency	419/1770 (23.7%)	37/316 (11.7%)	OR 1.05 (0.49 to 2.29)	237 per 1000	9 more per 1000 (from 105 fewer to 179 more)
Stereotypy	(assesse	d with: Validate	ed questionna	ire)							
915 (1 study)	no seriou s risk	no serious inconsistency	no serious indirectnes s	serious ²	undetecte d	⊕⊖⊝⊖ VERY LOW ² due to	362/881 (41.1%)	16/34 (47.1%)	OR 1.27 (0.64 to 2.53)	411 per 1000	59 more per 1000 (from 102

Quality asse	essment					Summary o	f findings		
	of bias				imprecision				fewer to 227 more)
1 I ² > 40% 2 Optimal info	ormation si	ize not met; sin	gle study						

A.2 Autism diagnosis

Table O.2: Autism diagnosis versus no autism diagnosis as a risk factor for challenging behaviour

Quality ass	essment						Summary	of findings			
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	Study ever	nt rates (%)	Relative effect	Anticipatec effects	l absolute
(studies) Follow up							With no autism diagnosis	With autism diagnosis	(95% CI)	Risk with no autism diagnosis	Risk difference with autism diagnosis (95% CI)
All aggress	ion (phys	ical, verbal and	destructive) (a	assessed with	n: Validated o	questionnaires, i	nterviews a	nd medical	records)		
1938 (2 studies)	no seriou s risk of bias	serious ¹	no serious indirectness	no serious imprecision	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to inconsistency	337/1718 (19.6%)	78/220 (35.5%)	OR 1.76 (1.17 to 2.65)	196 per 1000	104 more per 1000 (from 26 more to 197 more)
Destruction	of prope	rty (assessed w	ith: Questionr	naire and inte	rviews with b	oth service use	r and carer)				
2376 (2 studies)	no seriou s risk of bias	very serious ²	no serious indirectness	no serious imprecision	undetecte d	$\oplus \ominus \ominus$ VERY LOW ^{2,3} due to inconsistency, large effect	121/1285 (9.4%)	279/1091 (25.6%)	OR 5.6 (1.39 to 22.56)	94 per 1000	274 more per 1000 (from 32 more to 607 more)

Quality asse	essment						Summary	of findings			
Physical ag	gression	(assessed with	: Validated que	estionnaires,	interviews ar	nd medical recor	ds)				
5637 (4 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊕⊖ MODERATE ³ due to large effect	712/4468 (15.9%)	357/1169 (30.5%)	RR 2.80 (1.98 to 3.98)	159 per 1000	287 more per 1000 (from 156 more to 475 more)
Self-injury (assessed	with: Validated	l questionnaire	es and intervi	ews with bot	h service user a	nd carer)				
4338 (5 studies)	no seriou s risk of bias	very serious ²	no serious indirectness	no serious imprecision	undetecte d	$\oplus \ominus \ominus \ominus$ VERY LOW ^{2,3} due to inconsistency, large effect	416/3015 (13.8%)	390/1323 (29.5%)	OR 3.11 (1.81 to 5.35)	138 per 1000	194 more per 1000 (from 87 more to 323 more)
¹ I ² > 40% ² I ² > 75% ³ RR >2											

A.2.1 Degree of learning disability

Table O.3: Mild/moderate learning disability versus severe/profound learning disability as a risk factor for challenging behaviour

Quality ass	essmen	it			Summary of findings						
Participant s	Risk of	Inconsistenc y	Indirectne ss	Imprecisio n	PublicatioOverallStudy event rates (%)Relativn biasquality ofe effect		Study event rates (%)		Anticipate effects	ed absolute	
(studies) Follow up	bias					evidence	With Mild/ moderate LD	With Severe/profoun d LD	(95% CI)	Risk with Mild/ moderat e LD	Risk difference with Severe/profoun d LD (95% CI)
All aggress	sion (ph	ysical, verbal a	and destructi	ve) (assesse	ed with: Vali	dated questior	nnaires)				
1918 (2 studies)	no serio	very serious ¹	no serious indirectnes	no serious	undetecte d	$\begin{array}{c} \oplus \ominus \ominus \ominus \\ VERY \ LOW^1 \end{array}$	300/1398 (21.5%)	111/520 (21.3%)	OR 1.70	215 per 1000	103 more per 1000

Quality assessment								Summary of findings					
	us risk of bias		S	imprecisio n		due to inconsistenc y			(0.81 to 3.57)		(from 33 fewer to 279 more)		
Challengin	g behav	iour (global) (a	assessed wit	h: Survey)									
822 (1 study)	no serio us risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ²	undetecte d	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{2,3} due to imprecision, large effect	40/604 (6.6%)	51/218 (23.4%)	OR 4.31 (2.75 to 6.74)	66 per 1000	168 more per 1000 (from 97 more to 257 more)		
Destruction	n of prop	oerty (assesse	d with: Valid	ated questic	onnaire)								
3160 (1 study) 12 months	no serio us risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ²	undetecte d	 ⊕⊖⊖ VERY LOW² due to imprecision 	496/2165 (22.9%)	259/995 (26%)	OR 1.18 (1 to 1.41)	229 per 1000	31 more per 1000 (from 0 more to 66 more)		
Inappropria	ate sexu	al behaviour (a	assessed wit	h: Validated	questionna	ire)							
3160 (1 study) 12 months	no serio us risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ²	undetecte d	$\bigoplus \ominus \ominus \ominus$ VERY LOW ² due to imprecision	211/2165 (9.7%)	99/995 (9.9%)	OR 1.02 (0.8 to 1.32)	97 per 1000	2 more per 1000 (from 18 fewer to 27 more)		
Physical ag	ggressio	n – inpatient s	setting (asses	ssed with: S	urvey)								
11139 (1 study)	no serio us risk of bias	no serious inconsistenc y	serious ⁴	serious ²	undetecte d	 ⊕⊖⊖ VERY LOW^{2,4} due to indirectness, imprecision 	731/2485 (29.4%)	1885/8654 (21.8%)	OR 0.67 (0.6 to 0.74)	294 per 1000	76 fewer per 1000 (from 58 fewer to 94 fewer)		
Physical ag	ggressio	n – mixed sett	ing (assesse	d with: Valio	dated questi	ionnaires, inter	views, obse	rvations and med	lical recor	·ds)			
43864 (6 studies)	no serio us	very serious ¹	no serious indirectnes s	no serious imprecisio	undetecte d	⊕⊖⊝⊖ VERY LOW ¹ due to	2831/2079 4 (13.6%)	4189/23070 (18.2%)	OR 1.76 (1.4 to	136 per 1000	81 more per 1000 (from 45 more		

Quality ass	sessmen	t		Summary of	of findings								
	risk of bias			n		inconsistenc y			2.2)		to 121 more)		
Self-injury	Self-injury (assessed with: Validated questionnaires, surveys and medical records)												
85888 (12 studies) 0 to 36 months	no serio us risk of bias	very serious ¹	no serious indirectnes s	no serious imprecisio n	undetecte d	\bigcirc \bigcirc \bigcirc \lor VERY LOW ^{1,3} due to inconsistenc y, large effect	2144/4081 1 (5.3%)	7584/45077 (16.8%)	OR 3.75 (2.62 to 5.38)	53 per 1000	120 more per 1000 (from 74 more to 177 more)		
Stereotypy	(assess	ed with: Valid	ated questio	nnaires and	surveys)								
23946 (4 studies)	no serio us risk of bias	very serious ¹	no serious indirectnes s	no serious imprecisio n	undetecte d	\bigcirc \bigcirc \bigcirc \lor VERY LOW ^{1,3} due to inconsistenc y, large effect	1153/1784 7 (6.5%)	2740/6099 (44.9%)	OR 6.38 (1.42 to 28.65)	65 per 1000	241 more per 1000 (from 25 more to 600 more)		
Verbal agg	ression	(assessed with	h: Validated	questionnair	·e)								
3160 (1 study)	no serio us risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ²	undetecte d	$\bigcirc \bigcirc \bigcirc$ VERY LOW ² due to imprecision	896/2165 (41.4%)	293/995 (29.4%)	OR 0.59 (0.5 to 0.69)	414 per 1000	120 fewer per 1000 (from 86 fewer to 153 fewer)		
1 I ² > 75% 2 Optimal in 3 RR > 2	formatior	n size not met;	single study										

⁴ Partial applicability to review population – high risk inpatient

A.2.2 Expressive communication difficulties

Table O.4: Expressive communication difficulties versus no expressive communication difficulties as a risk factor for challenging behaviour

Quality as	sessmen	t					Summary of f	indings			
Participan	Risk of	Inconsisten	Indirectne	Imprecisi	Publicati	Overall	Study event ra	ites (%)	Relativ	Anticipated ab	solute effects
ts (studies) Follow up	bias	су	SS	on	on bias	quality of evidence	With no expressive communicati on difficulties	With expressive communicati on difficulties	e effect (95% CI)	Risk with no expressive communicati on difficulties	Risk difference with expressive communicati on difficulties (95% CI)
All aggres	sion (phy	vsical, verbal a	and destruct	ive) (asses	sed with: Va	alidated quest	ionnaire)				
1936 (2 studies)	no seriou s risk of bias	no serious inconsisten cy	no serious indirectne ss	no serious imprecisi on	undetect ed	⊕⊕⊝⊝ LOW	300/1310 (22.9%)	115/626 (18.4%)	OR 1.41 (1.08 to 1.86)	229 per 1000	66 more per 1000 (from 14 more to 127 more)
Physical a	ggressio	n- adult popu	lation (asses	ssed with: C	Questionnai	re)					
3662 (1 study)	seriou s ¹	no serious inconsisten cy	no serious indirectne ss	serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	784/2994 (26.2%)	250/668 (37.4%)	OR 1.69 (1.41 to 2.01)	262 per 1000	113 more per 1000 (from 72 more to 154 more)
Physical a	ggressio	n- mixed pop	ulation (asse	essed with:	Non-validat	ted questionna	aire)				
211 (1 study)	seriou s ³	no serious inconsisten cy	no serious indirectne ss	serious ²	undetect ed	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{2,3,4} due to risk of bias, imprecision,	52/166 (31.3%)	2/45 (4.4%)	OR 0.10 (0.02 to 0.44)	313 per 1000	270 fewer per 1000 (from 146 fewer to 304 fewer)

Quality as	ssessmen	t			Summary of findings									
						large effect								
Self-injury	y (assess	ed with: Ques	tionnaires, i	nterviews a	nd formal a	ssessments)								
7502 (9 studies) 0 to 3 years	no seriou s risk of bias	very serious⁵	no serious indirectne ss	no serious imprecisi on	undetect ed	 ⊕ ⊖ ⊖ ∨ERY LOW^{5,6} due to inconsisten cy, large effect 	821/5630 (14.6%)	566/1872 (30.2%)	OR 2.93 (1.8 to 4.78)	146 per 1000	188 more per 1000 (from 89 more to 304 more)			
Stereoty	/py (ass	essed with:	Validated	question	naire)									
915 (1 study)	no seriou s risk of bias	no serious inconsisten cy	no serious indirectne ss	serious ²	undetect ed	 ⊕⊖⊖ VERY LOW² due to imprecision 	290/769 (37.7%)	88/146 (60.3%)	OR 2.51 (1.74 to 3.6)	377 per 1000	226 more per 1000 (from 136 more to 308 more)			
² Optimal i	information	cklist for risk an n size not met; risk and outcor	single study		alidated									

A.2.4 Receptive communication difficulties

 Table 0.5: Receptive communication difficulties versus no receptive communication difficulties as a risk factor for challenging behaviour

Quality ass	sessme	nt					Summary of f	indings			
Participan	Risk		Overall	Study event ra	tes (%)	Relativ	Anticipated abs	solute effects			
ts (studies) Follow up	of bias	су	SS	on	on bias	quality of evidence	With no receptive communicati on difficulties	With receptive communicati on difficulties	e effect (95% CI)	Risk with no receptive communicati on difficulties	Risk difference with receptive communicati on difficulties (95% CI)
Self-injury	(assess	ed with: Ques	stionnaire ar	nd interview)						
1321 (3 studies) 0 to 3 years	no serio us risk of bias	no serious inconsisten cy	no serious indirectne ss	no serious imprecisi on	undetect ed	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ MODERAT \\ E^1 \\ due \text{ to large} \\ effect \end{array}$	148/1098 (13.5%)	82/223 (36.8%)	OR 3.46 (2.5 to 4.79)	135 per 1000	215 more per 1000 (from 146 more to 293 more)
¹ RR > 2											

A.2.5 Gender

Table O.6: Male gender versus female gender as a risk factor for challenging behaviour

Quality asse	essment						Summary	of findings			
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publicatio n bias	Overall quality of	Study even	t rates (%)	Relative effect	Anticipated effects	absolute
(studies) Follow up						evidence	With female gender	With male gender	(95% CI)	Risk with female gender	Risk difference with male gender (95% CI)
All aggressi	on (phys	ical, verbal and	destructive)	(assessed wit	th: Validated	questionnaire	and observa	tion)			
2046 (3 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	237/898 (26.4%)	238/1148 (20.7%)	OR 0.63 (0.51 to 0.79)	264 per 1000	80 fewer per 1000 (from 43 fewer to 109 fewer)
Challenging	behavio	ur (global) (ass	essed with: Va	alidated surve	ey)						
816 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to imprecision	34/370 (9.2%)	56/446 (12.6%)	OR 1.42 (0.9 to 2.23)	92 per 1000	34 more per 1000 (from 8 fewer to 92 more)
Destruction	of prope	rty (assessed w	vith: Validated	questionnai	re)						
3461 (2 studies) 0 to 12 months	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	0/3461 (0%)2	-2	Not estimabl e	See comment ²	-
Inappropriat	te sexual	behaviour (ass	essed with: Q	uestionnaire)						
3160	no	no serious	no serious	serious ¹	undetecte	$\oplus \Theta \Theta \Theta$	116/1527	194/1633	OR 1.64	76 per	43 more

Quality asse	essment						Summary	of findings			
(1 study) 12 months	seriou s risk of bias	inconsistency	indirectness		d	VERY LOW ¹ due to imprecision	(7.6%)	(11.9%)	(1.29 to 2.09)	1000	per 1000 (from 20 more to 71 more)
Physical ag	gression	(assessed with	: Validated qu	estionnaires	, interviews,	observations a	nd medical r	ecords)			
6925 (5 studies) 0 to 12 months	no seriou s risk of bias	serious ³	no serious indirectness	no serious imprecision	undetecte d	 ⊕⊖⊖ VERY LOW³ due to inconsistency 	0/6925 (0%)2	-2	Not estimabl e	See comment ²	-
Self-injury -	- mixed s	ettings (assess	ed with: Ques	tionnaire and	l survey)						
6174 (6 studies) 0 to 12 months	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	827/2820 (29.3%)	879/3354 (26.2%)	OR 0.81 (0.69 to 0.96)	293 per 1000	42 fewer per 1000 (from 8 fewer to 71 fewer)
Self-injury-	inpatient	setting (assess	sed with: Non-	validated que	estionnaire, s	survey and inter	view)				
18227 (5 studies) 0 to 3 years	no seriou s risk of bias	very serious ⁴	no serious indirectness	no serious imprecision	undetecte d	⊕⊖⊖⊖ VERY LOW ⁴ due to inconsistency	1008/824 6 (12.2%)	1220/998 1 (12.2%)	OR 0.97 (0.76 to 1.23)	122 per 1000	3 fewer per 1000 (from 27 fewer to 24 more)
Stereotypy	(assesse	d with: Validate	d questionnai	re)							
915 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to imprecision	169/411 (41.1%)	209/504 (41.5%)	RR 1.01 (0.86 to 1.18)	411 per 1000	4 more per 1000 (from 58 fewer to 74 more)
Verbal aggr	ession (a	ssessed with: \	/alidated ques	stionnaire)							
3461 (2 studies) 0 to 12 months	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	See comment	0/3461 (0%)2	-2	Not estimabl e	See comment ²	-

Quality assessment

Summary of findings

¹ Optimal information size not met; single study ² N/A; Generic inverse variance ³ $l^2 > 40\%$ ⁴ $l^2 > 75\%$

A.2.6 Mental health needs

Table 0.7: Mental health needs versus no mental health needs as a risk factor for challenging behaviour

Quality ass	essment						Summary of	f findings			
Participant s	Risk of bias	Inconsistency	Indirectnes s	Imprecisio n	Publicatio n bias	Overall quality of	Study event	rates (%)	Relative effect	Anticipated effects	absolute
(studies) Follow up						evidence	With no mental health needs	With mental health needs	(95% CI)	Risk with no mental health needs	Risk difference with mental health needs (95% CI)
All aggression (physical, verbal and destructive) (assessed with: Validated questionnaire)											
1938 (2 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	377/1837 (20.5%)	38/101 (37.6%)	OR 2.03 (1.3 to 3.15)	205 per 1000	139 more per 1000 (from 46 more to 243 more)
Destruction	of prope	erty (assessed v	vith: Validatec	l questionnai	re and surve	y)					
30874 (2 studies)	no seriou s risk of bias	very serious ¹	no serious indirectness	no serious imprecision	undetecte d	 ⊕⊖⊖ VERY LOW¹ due to inconsistency 	0/30874 (0%)2	-2	Not estimabl e	See comment ²	-

Quality asse	essment						Summary of	findings					
Physical ag	gression	(assessed with	: Validated qu	uestionnaire a	and survey)								
30874 (2 studies)	no seriou s risk of bias	very serious ¹	no serious indirectness	no serious imprecision	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to inconsistency	0/30874 (0%)2	-2	Not estimabl e	See comment ²	-		
Self-injury (assessed	d with: Validate	d questionnai	res and surve	∋y)								
32516 (3 studies) no seriou s risk of bias no serious inconsistency no serious indirectness no serious imprecision undetecte d ⊕⊕⊖⊖ LOW 2690/28860 (9.3%) 450/365 6 (12.3%) OR 1.4 (1.26 to 1.56) 93 per 1000 (from 21 more to 45 more)													
Stereotypy	Stereotypy (assessed with: Validated questionnaire and survey)												
31493 (2 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	1970/27876 (7.1%)	293/361 7 (8.1%)	OR 1.26 (1.1 to 1.43)	71 per 1000	17 more per 1000 (from 7 more to 27 more)		
Verbal aggr	ession (a	ssessed with:	Validated ques	stionnaire an	d survey)								
30874 (2 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊕⊖ MODERATE ³ due to large effect	0/30874 (0%)2	-2	Not estimabl e	See comment ²	-		
¹ I ² > 75% ² N/A; Generic inverse variance ³ RR > 2													

A.2.7 Mobility impairment

Table O.8: Mobility impairment versus no mobility impairment as a risk factor for challenging behaviour

Quality ass	essment						Summary of	f findings			
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publicatio n bias	Overall quality of	Study event	rates (%)	Relative effect	Anticipated effects	absolute
(studies) Follow up						evidence	With no impairmen t	With mobility impairment	(95% CI)	Risk with no impairmen t	Risk difference with mobility impairmen (95% CI)
All aggress	ion (phys	sical, verbal and	destructive)	(assessed wi	ith: Validated	l questionnair	·e)				
1023 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	 ⊕⊖⊖ VERY LOW¹ due to imprecision 	78/775 (10.1%)	22/248 (8.9%)	OR 0.87 (0.53 to 1.43)	101 per 1000	12 fewer per 1000 (from 45 fewer to 3 more)
Self-injury-	adult pop	oulation (asses	sed with: Valio	lated questic	onnaire)						
1023 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to imprecision	78/775 (10.1%)	22/248 (8.9%)	OR 0.87 (0.53 to 1.43)	101 per 1000	12 fewer per 1000 (from 45 fewer to 3 more)
Self-injury-	children	and young peo	ple population	(assessed w	with: Validate	d questionna	ire)				
147 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	⊕⊖⊖⊖ VERY LOW ¹ due to imprecision	64/134 (47.8%)	9/13 (69.2%)	OR 2.46 (0.72 to 8.38)	478 per 1000	215 more per 1000 (from 81 fewer to 407 more)

¹ Optimal information size not met; single study

A.2.8 Visual impairment

Table O.9: Visual impairment versus no visual impairment as a risk factor for challenging behaviour

Quality asse	essment						Summary o	f findings			
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publicatio n bias	Overall quality of	Study event	rates (%)	Relative effect	Anticipated effects	absolute
(studies) Follow up						With No impairmen t	With Visual impairmen t	(95% CI)	Risk with No impairmen t	Risk difference with Visual impairment (95% CI)	
All aggressi	ion (phys	ical, verbal and	destructive)	(assessed wit	th: Validated	questionnair	e)				
1938 (2 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	349/1422 (24.5%)	66/516 (12.8%)	OR 1.22 (0.78 to 1.92)	245 per 1000	39 more per 1000 (from 43 fewer to 139 more)
Self-injury (assessed	d with: Validated	d questionnai	re)							
2086 (3 studies)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	no serious imprecision	undetecte d	⊕⊕⊝⊝ LOW	384/1564 (24.6%)	73/522 (14%)	OR 1.45 (1.02 to 2.06)	246 per 1000	75 more per 1000 (from 4 more to 156 more)
Stereotypy	(assesse	d with: Validate	d questionnai	ire)							
915 (1 study)	no seriou s risk of bias	no serious inconsistency	no serious indirectness	serious ¹	undetecte d	 ⊕⊖⊖ VERY LOW¹ due to imprecision 	356/880 (40.5%)	22/35 (62.9%)	OR 2.49 (1.24 to 5.01)	405 per 1000	224 more per 1000 (from 53 more to 368 more)

A.3 Interventions aimed at the prevention of behaviour that challenges

A.3.1 Educational intervention versus attention control

 Table O.10: Learning Experiences and Alternative Program for Pre-schoolers and Their Parents (LEAP) – full replication condition versus manual-only attention control

Quality ass	essment						Summar	y of findings			
Participant s	Risk of bias	Inconsistenc y	Indirectnes s	Imprecisio n	Publicatio n bias	Overall quality of	Study ev	ent rates (%)	Relative effect	Anticipate effects	ed absolute
(studies) Follow up						evidence	With attentio n control	With educationa I interventio n	(95% CI)	Risk with attentio n control	Risk difference with educational intervention (95% CI)
Behaviour f	hat challe	nges (severity)	- post-treatm	nent (measur	ed with: Cha	nge score ¹ ; Be	etter indic	ated by lower	values)		
294 (1 study)	serious 2	no serious inconsistenc y	serious ³	serious ⁴	undetecte d	⊕⊖⊖⊖ VERY LOW ^{2,3,4} due to risk of bias, indirectness , imprecision	117	177	-		The mean behaviour that challenges (severity) – post- treatment in the intervention groups was 0.19 standard deviations lower (0.42 lower to 0.04 higher)
Adaptive fu	nctioning	(social) - post-	treatment (Be	etter indicate	d by lower va	alues)					
294 (1 study)	serious 2	no serious inconsistenc y	serious ³	serious ⁴	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3,4} due to risk of bias, 	117	177	-		The mean adaptive functioning (social) – post- treatment in the

Quality ass	essment						Summar	y of findings		
						indirectness , imprecision				intervention groups was 0.76 standard deviations higher (0.52 to 1 higher)
Adaptive fu	unctioning	(communicatio	on) – post-trea	atment (Bette	r indicated b	y lower values	5)			
294 (1 study)	serious 2	no serious inconsistenc y	serious ³	serious ⁴	undetecte d	⊕⊖⊖ VERY LOW ^{2,3,4} due to risk of bias, indirectness , imprecision	117	177	-	The mean adaptive functioning (communication) – post-treatment in the intervention groups was 0.94 standard deviations higher (0.7 to 1.19 higher)

¹ Due to significant baseline differences, standard deviation of change and estimates of mean change were derived using initial and final mean values and utilising r = 0.5. Sensitivity analyses were used to explore the impact of altering assumptions about the calculation of the effect size, but this resulted in no change to conclusions.

² Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

A.3.2 Home-based EBI versus centre-based EBI

Table 0.11: Home-based Building Blocks programme versus centre-based Building Blocks programme

Quality ass	sessment						Summary of	of findings			
Participant	Risk of	Inconsistenc	Indirectnes	Imprecisio	Publicatio	Overall	Study event	t rates (%)	Relativ	Anticipated	absolute effects
s (studies) Follow up	bias	У	S	n	n bias	quality of evidence	With centre- based early behaviour al interventio n	With home- based early behaviour al interventio n	e effect (95% CI)	Risk with centre- based early behaviour al interventio n	Risk difference with home- based early behavioural intervention (95% CI)
Behaviour	that challe	enges (severity	/) – post-treat	ment (Bette	r indicated b	y lower valu	es)				
44 (1 study)	serious 1	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetecte d	⊕⊖⊖⊖ VERY LOW ^{1,2} due to risk of bias, imprecisio n	22	22	-		The mean behaviour that challenges (severity) – post-treatment in the intervention groups was 0.11 standard deviations lower (0.7 lower to 0.48 higher)
Adaptive fu	unctioning	g (social) – pos	t-treatment (E	Better indica	ted by lower	values)					
56 (1 study)	serious 1	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetecte d	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecisio 	29	27	-		The mean adaptive functioning (social) – post- treatment in the intervention

Quality ass	essment						Summary of	of findings		
						n				groups was 0.63 standard deviations lov (1.17 to 0.09 lower)
Adaptive fu	unctioning	(communicati	ion) – post-tre	eatment (Bet	ter indicated	l by lower va	alues)			
55 (1 study)	serious 1	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetecte d	⊕⊖⊖⊖ VERY LOW ^{1,2} due to risk of bias, imprecisio n	29	26	-	The mean adaptive functioning (communicat) – post- treatment in t intervention groups was 0.46 standard deviations lov (1 lower to 0. higher)

² Optimal information size not met; small, single study

A.3.3 EIBI versus parent training

Table O.12: EIBI (UCLA model) versus parent training

Quality ass	essment						Summa	r <mark>y of f</mark> i	ndings		
Participant s	Risk of bias	Inconsistency	Indirectnes s	Imprecisio n	Publication bias	Overall quality of	Study ev rates (%		Relative effect	Anticipat	ed absolute effects
(studies) Follow up						evidence	With parent training	Wit h EIB I	(95% CI)	Risk with parent training	Risk difference with EIBI (95% CI)

Quality ass	sessment						Summa	ary of f	indings	
Behaviour	that challe	nges (severity)	- post-treatn	nent (measure	ed with: Parer	nt-rated; Better	indicate	d by lo	wer values)	
28 (1 study)	no serious risk of bias	no serious inconsistency	serious ¹	very serious ²	undetected	 ⊕⊖⊖ VERY LOW^{1,2} due to indirectness, imprecision 	13	15	-	The mean behaviour that challenges (severity) – post- treatment in the intervention groups was 0.36 standard deviations lower (1.1 lower to 0.39 higher)
Behaviour	that challe	nges (severity)	– post-treatn	nent (measure	ed with: Teacl	ner-report; Bett	ter indica	ted by	lower values)	
28 (1 study)	no serious risk of bias	no serious inconsistency	serious ¹	very serious ²	undetected	 ⊕⊖⊖ VERY LOW^{1,2} due to indirectness, imprecision 	13	15	-	The mean behaviour that challenges (severity) – post- treatment in the intervention groups was 0.47 standard deviations higher (0.28 lower to 1.23 higher)
Adaptive fu	unctioning	(communicatio	n) – post-trea	atment (Better	indicated by	lower values)				
28 (1 study)	no serious risk of bias	no serious inconsistency	serious ¹	very serious ²	undetected	 ⊕⊖⊖ VERY LOW^{1,2} due to indirectness, imprecision 	13	15	-	The mean adaptive functioning (communication) – post-treatment in the intervention groups was 0.63 standard deviations higher (0.13 lower to 1.39 higher)

Quality asso	essment						Summa	r <mark>y of</mark> f	indings		
Adaptive fu	nctioning	(global) – post-	treatment (Be	tter indicated	by lower val	ues)					
28 (1 study)	no serious risk of bias	no serious inconsistency	serious ¹	very serious ²	undetected	 ⊕⊖⊖ ∨ERY LOW^{1,2} due to indirectness, imprecision 	13	15	-	f i (((The mean adaptive functioning (global) – post-treatment in the ntervention groups was 0.11 standard deviations higher (0.64 lower to 0.85 higher)
		s: autism populat ize not met; sma			concerning lea	arning disability					

A.3.4 High supervision EIBI versus low supervision EIBI

 Table 0.13:
 High supervision EIBI (clinic-directed UCLA model) versus low supervision EIBI (parent-directed UCLA model)

Quality ass	essment						Summary of	of findings			
Participant	Risk of	Inconsistenc	Indirectnes		Overall	Study event	t rates (%)	Relativ	Anticipated	absolute effects	
s (studies) Follow up	bias	У	S	n	n bias	quality of evidence	With low supervisio n EIBI (parent- directed)	With high supervisio n EIBI (clinic- directed)	e effect (95% CI)	Risk with low supervisio n EIBI (parent- directed)	Risk difference with high supervision EIBI (clinic- directed) (95% CI)
Adaptive fu	Inctioning	g (communicati	ion) -post-tre	atment (Bette	er indicated	by lower valu	es)				
23 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetecte d	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk	10	13	-		The mean adaptive functioning (communication

Quality assessment				Summary of fir	ndings	
			of bias, indirectnes s, imprecision) -post- treatment in the intervention groups was 0.25 standard deviations lower (1.08 lower to 0.57 higher)
 ¹ Crucial limitation for one crit ² Applicability concerns: autis ³ Optimal information size no 	m population; no inform	nation reported concerni			in the estimate of effect	

A.3.5 Parent training versus any control

Table 0.14: Parent training (plus centre based EBI) versus treatment as usual (centre-based EBI)

Quality asso	essment						Summa	ary of find	dings		
Participant s	Risk of bias	5		Imprecisio n	Publication bias	Overall quality of	Study e rates (%		Relative effect	Anticipa	ted absolute effects
(studies) Follow up						evidence	With contro I	With parent trainin g	(95% CI)	Risk with contro I	Risk difference with parent training (95% CI)
Behaviour t	hat challer	nges (severity) -	post-treatmer	nt (Better ind	icated by low	er values)					
57 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	28	29	-		The mean behaviour that challenges (severity) – post- treatment in the intervention groups

Quality asse	essment						Summa	ary of find	lings	
										was 0.4 standard deviations lower (0.93 lower to 0.12 higher)
Behaviour t	hat challen	ges (severity) –	follow up (Be	tter indicated	l by lower val	lues)				
117 (2 studies) 26 to 52 weeks	serious ²	no serious inconsistency	no serious indirectness	serious ³	undetecte d	$\oplus \oplus \ominus \ominus$ LOW ^{2,3} due to risk of bias, imprecision	58	59	-	The mean behaviour that challenges (severity) – follow up in the intervention groups was 0.37 standard deviations lower (0.79 lower to 0.05 higher)
Adaptive fu	nctioning (global) – post-ti	eatment (Bette	er indicated b	oy lower valu	es)				
58 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	28	30	-	The mean adaptive functioning (global) – post-treatment in the intervention groups was 0.25 standard deviations higher (0.27 lower to 0.77 higher)
Adaptive fu	nctioning (global) – follow	up (Better ind	icated by low	/er values)					
119 (2 studies) 26 to 52 weeks	serious ²	no serious inconsistency	no serious indirectness	serious ³	undetecte d	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{2,3} due to risk of bias, imprecision	56	63	-	The mean adaptive functioning (global) – follow-up in the intervention groups was 0.52 standard deviations higher

Quality ass	essment						Summ	ary of fine	dings			
											(0.15 to 0.88 higher)	
Adaptive functioning (communication) – follow-up (Better indicated by lower values)												
68 (1 study) 26 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	33	35	-		The mean adaptive functioning (communication) – follow-up in the intervention groups was 0.75 standard deviations higher (0.26 to 1.25 higher)	
	mation is fro	ze not met; small om studies at moo ze not met		as								

- A.4 Interventions aimed at reducing health risks and increasing understanding of physical illness in relation to the prevention or management of behaviour that challenges
- A.4.1 Hand-held health record versus treatment as usual

Table O.15: Advocacy Skills Kit Diary or Personal Health Profile versus treatment as usual

Quality ass	essment						Summary	of finding	IS		
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publication bias	Overall quality of	Study ever (%)	nt rates	Relative effect	Anticipated effects	absolute
(studies) Follow up						evidence	With treatment as usual	With hand- held health record	(95% CI)	Risk with treatment as usual	Risk difference with hand- held health record (95% CI)

Quality ass	essment						Summary	of finding	S		
Health pror	notion (blo	od pressure ch	ecked)								
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊝⊖ LOW¹ due to imprecision	32/68 (47.1%)	28/51 (54.9%)	RR 1.17 (0.82 to 1.66)	471 per 1000	80 more per 1000 (from 85 fewer to 311 more)
Health pror	notion (cor	nstipation inves	tigation)								
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊝⊝ LOW ¹ due to imprecision	1/68 (1.5%)	5/51 (9.8%)	RR 6.67 (0.8 to 55.33)	15 per 1000	83 more per 1000 (from 3 fewer to 799 more)
Health pror	notion (hea	aring test)									
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \ominus \ominus \\ LOW^1 \\ due to \\ imprecision \end{array}$	2/68 (2.9%)	3/51 (5.9%)	RR 2 (0.35 to 11.53)	29 per 1000	29 more per 1000 (from 19 fewer to 310 more)
Health pror	notion (vis	ion test)									
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	4/68 (5.9%)	7/51 (13.7%)	RR 2.33 (0.72 to 7.55)	59 per 1000	78 more per 1000 (from 16 fewer to 385 more)
Health pror	notion (wei	ight measured)									
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	17/68 (25%)	18/51 (35.3%)	RR 1.41 (0.81 to 2.46)	250 per 1000	102 more per 1000 (from 47 fewer to 365 more)
Health pror	notion (wei	ight manageme	nt plan)								
119	no	no serious	no serious	very	undetecte	$\oplus \oplus \ominus \ominus$	12/68	5/51	RR 0.56	176 per	78 fewer per

Quality ass	essment						Summary	of finding	S		
(1 study) 52 weeks	serious risk of bias	inconsistency	indirectness	serious ¹	d	LOW ¹ due to imprecision	(17.6%)	(9.8%)	(0.21 to 1.48)	1000	1000 (from 139 fewer to 85 more)
Health pron	notion (epi	lepsy review)									
119 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	8/68 (11.8%)	11/51 (21.6%)	RR 1.83 (0.8 to 4.23)	118 per 1000	98 more per 1000 (from 24 fewer to 380 more)
Service user by higher va		e of health proble	ms (measured	with: Knowlec	lge of Health	Problems and	Terminology	Checklist	(unvalidate	d measure);	Better indicated
66 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊖⊖⊖ VERY LOW ^{1,2} due to risk of bias, imprecision	32	34	-		The mean service user knowledge of health problems in the intervention groups was 0.32 standard deviations lower (0.81 lower to 0.16 higher)
Carer know indicated b		ealth problems (llues)	measured wit	h: Knowledge	e of Health P	roblems and ⁻	Ferminology	/ Checklis	t (unvalida	ted measur	e); Better
144 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2} due to risk of bias, imprecision	74	70	-		The mean carer knowledge of health problems in the

Quality asse	essment						Summary	of finding	S		
											intervention groups was 0 standard deviations higher (0.33 lower to 0.33 higher)
Carer satisf	action (Bet	tter indicated by	/ lower values)							
101 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	52	49	-		The mean carer satisfaction in the intervention groups was 0 standard deviations higher (0.39 lower to 0.39 higher)
Service use	r satisfacti	ion (Better indic	ated by lower	values)							
36 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	20	16	-		The mean service user satisfaction in the intervention groups was 0.6 standard deviations higher (0.08 lower to 1.27 higher)
Premature of	death										
169	serious ²	no serious	no serious	very	undetecte	$\Theta \Theta \Theta \Theta$	2/88	5/81	RR 2.72	23 per	39 more per

		Summary of findings					
(2.3%) (6.	6.2%) (0.54 to 13.61)	(fro fev	00 om 10 wer to 287 ore)				
		13.01)	ŕev				

² Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

A.4.2 Annual health check versus treatment as usual

Table O.16: Comprehensive Health Assessment Program versus treatment as usual

Quality asso	essment						Summary	Summary of findings					
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publication bias	Overall quality of evidence	Study ever (%)	nt rates	Relative effect	Anticipated absolute effects			
(studies) Follow up							With treatment as usual	With annual health check	(95% CI)	Risk with treatment as usual	Risk difference with annual health check (95% CI)		
Health prom	notion (blo	ood pressure ch	necked)										
574 (2 studies) 52 weeks	no serious risk of bias	very serious ¹	no serious indirectness	serious ²	undetecte d	 ⊕⊖⊖ VERY LOW^{1,2} due to inconsistency, imprecision 	131/287 (45.6%)	143/287 (49.8%)	RR 1.09 (0.92 to 1.30)	456 per 1000	41 more per 1000 (from 37 fewer to 137 more)		
Health prom	notion (co	nstipation inve	stigation)										
121 (1 study) 52 weeks	no serious risk of	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊕⊝⊖ LOW ³ due to	1/68 (1.5%)	4/53 (7.5%)	RR 5.13 (0.59 to 44.58)	15 per 1000	61 more per 1000 (from 6		

Quality ass	essment						Summary	of finding	s		
	bias					imprecision					fewer to 641 more)
Health pron	notion (he	aring test)									
574 (2 studies) 52 weeks	no serious risk of bias	serious ⁴	no serious indirectness	serious ²	undetecte d	⊕⊕⊖⊖ LOW ^{2,4} due to inconsistency, imprecision	3/287 (1%)	42/287 (14.6%)	RR 12.22 (2.43 to 61.49)	10 per 1000	117 more per 1000 (from 15 more to 632 more)
Health pron	notion (vis	sion test)									
574 (2 studies) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ²	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ MODERATE^2 \\ due to \\ imprecision \end{array}$	16/287 (5.6%)	60/287 (20.9%)	RR 3.75 (2.21 to 6.36)	56 per 1000	153 more per 1000 (from 67 more to 299 more)
Health pron	notion (ac	uity corrected b	oy glasses)								
453 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊕⊖⊖ LOW ³ due to imprecision	0/219 (0%)	3/234 (1.3%)	RR 6.55 (0.34 to 126.14)	0 per 1000	-
Health pron	notion (ot	oscopic examin	ation)								
453 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊕⊝⊝ LOW ³ due to imprecision	50/219 (22.8%)	92/234 (39.3%)	RR 1.72 (1.29 to 2.3)	228 per 1000	164 more per 1000 (from 66 more to 297 more)
Health pron	notion (we	eight measurem	ent)								
574 (2 studies) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ²	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ MODERATE^2 \\ due to \\ imprecision \end{array}$	53/287 (18.5%)	129/287 (44.9%)	RR 2.46 (1.87 to 3.23)	185 per 1000	270 more per 1000 (from 161 more to 412 more)

Quality ass	essment						Summary	of finding	S		
Health pror	notion (we	eight manageme	ent plan)								
574 (2 studies) 52 weeks	no serious risk of bias	serious ⁴	no serious indirectness	serious ²	undetecte d	⊕⊕⊖⊖ LOW ^{2,4} due to inconsistency, imprecision	13/287 (4.5%)	22/287 (7.7%)	RR 2.32 (0.66 to 8.14)	45 per 1000	60 more per 1000 (from 15 fewer to 323 more)
Health pror	notion (ep	oilepsy review)									
121 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigcirc \bigcirc \\ LOW^3 \\ due to \\ imprecision \end{array}$	8/68 (11.8%)	9/53 (17%)	RR 1.44 (0.6 to 3.49)	118 per 1000	52 more per 1000 (from 47 fewer to 293 more)
Identificatio	on of phys	ical health prob	olem (hearing l	oss)							
453 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊕⊝⊖ LOW ³ due to imprecision	0/219 (0%)	15/234 (6.4%)	RR 29.02 (1.75 to 482.11)	0 per 1000	-
Identificatio	on of phys	ical health prob	olem (visual im	pairment)							
453 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigcirc \bigcirc \\ LOW^3 \\ due to \\ imprecision \end{array}$	1/219 (0.46%)	7/234 (3%)	RR 6.55 (0.81 to 52.82)	5 per 1000	25 more per 1000 (from 1 fewer to 237 more)
Identificatio	on of phys	ical health prob	olem (obesity)								
453 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊕⊖⊖ LOW ³ due to imprecision	4/219 (1.8%)	17/234 (7.3%)	RR 3.98 (1.36 to 11.64)	18 per 1000	54 more per 1000 (from 7 more to 194 more)
Premature	death										
453	no	no serious	no serious	very	undetecte	$\oplus \oplus \ominus \ominus$	1/219	1/234	RR 0.94	5 per	0 fewer per

Quality asso			Summary of findings								
(1 study) 52 weeks	serious risk of bias	inconsistency	indirectness	serious ³	d	LOW ³ due to imprecision	(0.46%)	(0.43%)	(0.06 to 14.87)	1000	1000 (from 4 fewer to 63 more)
1 l ² > 75% ² Optimal inf ³ Optimal inf ⁴ l ² > 40%		size not met size not met; sma	all, single study								

A.4.3 Annual health check versus hand-held health record

Table 0.17: Comprehensive Health Assessment Program versus Advocacy Skills Kit Diary

Quality asse	essment						Summary of findings					
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publication bias	Overall quality of	Study ever (%)	nt rates	Relative effect	Anticipated absolute effects		
(studies) Follow up						evidence	With hand- held health record	With annual health check	(95% CI)	Risk with hand- held health record	Risk difference with annual health check (95% CI)	
Health prom	otion (blo	od pressure che	ecked)									
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	⊕⊕⊖⊖ LOW ¹ due to imprecision	28/51 (54.9%)	26/53 (49.1%)	RR 0.89 (0.62 to 1.29)	549 per 1000	60 fewer per 1000 (from 209 fewer to 159 more)	
Health prom	otion (co	nstipation invest	tigation)									
104 (1 study)	no serious	no serious inconsistency	no serious indirectness	very serious ¹	undetected	$\begin{array}{c} \oplus \oplus \ominus \ominus \\ LOW^1 \end{array}$	5/51 (9.8%)	4/53 (7.5%)	RR 0.77 (0.22 to	98 per 1000	23 fewer per 1000	

Quality ass	essment						Summary	of finding	s		
52 weeks	risk of bias					due to imprecision			2.71)		(from 76 fewer to 168 more)
Health pror	notion (he	aring test)									
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	⊕⊕⊝⊖ LOW ¹ due to imprecision	3/51 (5.9%)	10/53 (18.9%)	RR 3.21 (0.94 to 10.99)	59 per 1000	130 more pe 1000 (from 4 fewe to 588 more)
Health pror	notion (vis	sion test)									
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	7/51 (13.7%)	11/53 (20.8%)	RR 1.51 (0.64 to 3.60)	137 per 1000	70 more per 1000 (from 49 fewer to 357 more)
Health pror	notion (we	eight measured)									
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	⊕⊕⊝⊖ LOW ¹ due to imprecision	18/51 (35.3%)	29/53 (54.7%)	RR 1.55 (0.99 to 2.42)	353 per 1000	194 more per 1000 (from 4 fewer to 501 more)
Health pror	notion (we	ight manageme	nt plan)								
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	⊕⊕⊝⊖ LOW ¹ due to imprecision	5/51 (9.8%)	15/53 (28.3%)	RR 2.89 (1.13 to 7.36)	98 per 1000	185 more per 1000 (from 13 more to 624 more)
Health pror	notion (ep	ilepsy review)									
104 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetected	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	11/51 (21.6%)	9/53 (17%)	RR 0.79 (0.36 to 1.74)	216 per 1000	45 fewer per 1000 (from 138 fewer to 160 more)

Quality assessment

Summary of findings

¹ Optimal information size not met; small, single study

A.4.4 Annual health check and hand-held health record versus treatment as usual

 Table 0.18: Comprehensive Health Assessment Program and Advocacy Skills Kit Diary versus treatment as usual

Quality ass	essment						Summary of findings					
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publication bias	Overall quality of	Study ever	nt rates (%)	Relative effect	Anticipated effects	absolute	
(studies) Follow up						evidence	With treatment as usual	With annual health check + hand- held health record	(95% CI)	Risk with treatment as usual	Risk difference with annual health check + hand-held health record (95% CI)	
Health pron	notion (blo	ood pressure ch	necked)									
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	32/68 (47.1%)	46/70 (65.7%)	RR 1.4 (1.03 to 1.89)	471 per 1000	188 more per 1000 (from 14 more to 419 more)	
Health pron	notion (co	nstipation inve	stigation)									
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^1 \\ due to \\ imprecision \end{array}$	1/68 (1.5%)	4/70 (5.7%)	RR 3.89 (0.45 to 33.89)	15 per 1000	42 more per 1000 (from 8 fewer to 484 more)	
Health prom	notion (he	aring test)										
138	no	no serious	no serious	very	undetecte	$\oplus \oplus \ominus \ominus$	2/68	10/70	RR 4.86	29 per	114 more	

Quality ass	essment						Summary	of findings	5		
(1 study) 52 weeks	serious risk of bias	inconsistency	indirectness	serious ¹	d	LOW ¹ due to imprecision	(2.9%)	(14.3%)	(1.1 to 21.36)	1000	per 1000 (from 3 more to 599 more
Health pron	notion (vis	sion test)									
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊝⊖ LOW¹ due to imprecision	4/68 (5.9%)	20/70 (28.6%)	RR 4.86 (1.75 to 13.47)	59 per 1000	227 more per 1000 (from 44 more to 734 more)
Health pron	notion (we	eight measured)									
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊝⊖ LOW ¹ due to imprecision	17/68 (25%)	41/70 (58.6%)	RR 2.34 (1.48 to 3.7)	250 per 1000	335 more per 1000 (from 120 more to 675 more)
Health pron	notion (we	eight manageme	ent plan)								
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	12/68 (17.6%)	7/70 (10%)	RR 0.57 (0.24 to 1.35)	176 per 1000	76 fewer per 1000 (from 134 fewer to 62 more)
Health pron	notion (ep	ilepsy review)									
138 (1 study) 52 weeks	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ¹	undetecte d	⊕⊕⊖⊖ LOW ¹ due to imprecision	8/68 (11.8%)	7/70 (10%)	RR 0.85 (0.33 to 2.22)	118 per 1000	18 fewer per 1000 (from 79 fewer to 144 more)

A.5 Environmental change interventions aimed at reducing and managing behaviour that challenges

A.5.1 Sensory intervention versus any control

Table O.19: Multisensory room or vibroacoustic chair versus any control

Quality asso	essment						Summa	ary of findings	5		
Participant s	Risk of bias	Inconsistency	Indirectness	Imprecisio n	Publication bias	Overall quality of	Study e (%)	event rates	Relative effect	Anticipa effects	ated absolute
(studies) Follow up						evidence	With any contro I	With sensory intervention	(95% CI)	Risk with any contro I	Risk difference with sensory intervention (95% CI)
Targeted be	haviour th	nat challenges (global) – post-	-treatment (m	easured with	h: Change sco	ore ¹ ; Bett	ter indicated k	oy lower va	alues)	
89 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	41	48	-		The mean targeted behaviour that challenges (global) – post- treatment in the intervention groups was 1.69 standard deviations higher (1.2 to 2.18 higher)
Targeted be	haviour th	nat challenges (global) – follov	w-up (measu	red with: Cha	inge score ¹ ; E	Better ind	dicated by low	ver values)		
89 (1 study) 12 weeks	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊖⊖⊖ VERY LOW ^{2,3}	41	48	-		The mean targeted behaviour that

Quality ass	essment						Summ	ary of finding	5		
						due to risk of bias, imprecision					challenges (global) – follow- up in the intervention groups was 0.00 standard deviations higher (0.42 lower to 0.42 higher)
Targeted be	ehaviour th	at challenges (self-injurious	behaviour, se	everity) – pos	st-treatment (E	Better in	dicated by lov	ver values)		
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	10	10	-		The mean targeted behaviour that challenges (self- injurious behaviour, severity) – post- treatment in the intervention groups was 0.2 standard deviations lower (1.08 lower to 0.68 higher)
Targeted be	ehaviour th	at challenges (self-injurious	behaviour, fr	equency) – p	ost-treatment	(Better	indicated by I	ower value	s)	
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	10	10	-		The mean targeted behaviour that challenges (self- injurious behaviour, frequency) – post-treatment in the intervention

Quality ass	essment						Summa	ary of finding	S		
											groups was 0.25 standard deviations lower (1.14 lower to 0.63 higher)
Targeted be	ehaviour th	nat challenges (stereotypical	behaviour, se	everity) – pos	t-treatment (E	Better ind	licated by low	ver values)		
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	⊕⊖⊖⊖ VERY LOW ^{2,3} due to risk of bias, imprecision	10	10	-		The mean targeted behaviour that challenges (stereotypical behaviour, severity) – post- treatment in the intervention groups was 0.33 standard deviations higher (0.55 lower to 1.21 higher)
Targeted be	ehaviour th	nat challenges (stereotypical	behaviour, fr	equency) – p	ost-treatment	(Better i	ndicated by lo	ower value	s)	
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	10	10	-		The mean targeted behaviour that challenges (stereotypical behaviour, frequency) – post-treatment in the intervention groups was 0.22 standard deviations lower (1.1 lower to 0.66

Quality ass	sessment						Summ	ary of finding	6	
										higher)
Targeted b	ehaviour th	nat challenges (aggressive/ de	estructive be	haviour, seve	erity) – post-tr	reatment	t (Better indica	ated by lower value	es)
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	10	10		The mean targeted behaviour that challenges (aggressive/ destructive behaviour, severity) – post- treatment in the intervention groups was 0.15 standard deviations lower (1.03 lower to 0.72 higher)
Targeted b	ehaviour th	nat challenges (aggressive/ de	estructive be	haviour, freq	uency) – post	-treatme	ent (Better ind	icated by lower val	ues)
20 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	10	10		The mean targeted behaviour that challenges (aggressive/ destructive behaviour, frequency) – post-treatment in the intervention groups was 0.22 standard deviations lower (1.1 lower to 0.66 higher)

Quality ass	essment						Summ	ary of finding	5	
Adaptive fu	unctioning -	– post-treatmer	nt (measured v	vith: Change	score ¹ ; Bette	er indicated by	y higher	values)		
89 (1 study)	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	41	48	-	The mean adaptive functioning – post-treatment in the intervention groups was 1.12 standard deviations lower (1.57 to 0.67 lower)
Adaptive fu	unctioning -	– follow-up (me	asured with: 0	Change score	e ¹ ; Better ind	icated by high	ner value	es)		
89 (1 study) 12 weeks	serious ²	no serious inconsistency	no serious indirectness	very serious ³	undetecte d	 ⊕⊖⊖ VERY LOW^{2,3} due to risk of bias, imprecision 	41	48	-	The mean adaptive functioning – follow-up in the intervention groups was 0.48 standard deviations lower (0.9 to 0.05 lower)

¹ Due to significant baseline differences, standard deviation of change and estimates of mean change were derived using initial and final mean values and utilising r = 0.5. Sensitivity analyses were used to explore the impact of altering assumptions about the calculation of the effect size, but this resulted in no change to conclusions.

² Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

³ Optimal information size not met; small, single study

A.5.2 Structured activity versus unstructured activity

 Table O.20: Special Olympics Sports Skill Instructional Program versus free play

Quality asso	essment						Summary of	findings			
Participant s	Risk of bias	Inconsistenc y	Indirectnes s	Imprecisio n	Publicatio n bias	Overall quality of	Study event i	ates (%)	Relative effect	Anticipated a effects	bsolute
(studies) Follow up						evidence	With unstructure d activity	With structure d activity	(95% CI)	Risk with unstructure d activity	Risk difference with structured activity (95% CI)
Targeted be	haviour t	hat challenges	(severity) – pe	ost-treatment	t (measured	with: Change	e score ¹ ; Bette	r indicated	by lower v	alues)	
26 (1 study)	2 2	no serious inconsistency	no serious indirectnes s	very serious ³	undetecte d	⊕⊖⊖⊖ VERY LOW ^{2,3} due to risk of bias, imprecisio n	13	13	-		The mean targeted behaviour that challenges (severity) – post- treatment in the interventio n groups was 0.87 standard deviations lower (1.68 to 0.06 lower)
Targeted be	haviour t	hat challenges	(severity) – fo	ollow-up (mea	asured with:	Change scor	e ¹ ; Better indi	cated by lov	wer values	5)	
26	serious	no serious	no serious	very	undetecte	$\oplus \Theta \Theta \Theta$	13	13	-		The mean

Quality ass	essment						Summary of	findings		
(1 study) 6 weeks	2	inconsistency	indirectnes s	serious ³	d	VERY LOW ^{2,3} due to risk of bias, imprecisio n				targeted behaviour that challenges (severity) – follow-up in the interventio n groups was 0.95 standard deviations lower (1.77 to 0.13 lower)

¹ Due to significant baseline differences, standard deviation of change and estimates of mean change were derived using initial and final mean values and utilising r = 0.5. Sensitivity analyses were used to explore the impact of altering assumptions about the calculation of the effect size, but this resulted in no change to conclusions.

² Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
 ³ Optimal information size not met; small, single study

A.6 Parent training interventions aimed at reducing and managing behaviour that challenges

A.6.1 Parent training versus any control

Table 0.21: Parent training versus any control

Quality a	ssessm	ent					Summ	ary of fin	dings		
Participa nts	Risk of	Inconsisten cy	Indirectne ss	Imprecisio n	Publication bias	Overall quality of evidence	Study e rates (9		Relati ve	Anticip	ated absolute effects
(studies) Follow up	bias						With any contr ol	With parent trainin g	effect (95% CI)	Risk with any contr ol	Risk difference with parent training (95% CI)
Targeted	behavi	our that challe	nges (severi	ty) – post-tre	eatment (Bette	er indicated by lowe	er values	5)			
841 (14 studies)	serio us ¹	no serious inconsisten cy	no serious indirectnes s	no serious imprecisio n	undetected	 ⊕⊕⊕⊖ MODERATE¹ due to risk of bias 	390	451	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.41 standard deviations lower (0.58 to 0.24 lower)
Targeted	behavi	our that challe	nges (severi	ty) – follow-ι	up (Better indi	cated by lower valu	ues)				
342 (3 studies) 26- 52 weeks	serio us ¹	no serious inconsisten cy	serious ²	serious ³	reporting bias strongly suspected ⁴	 ⊕⊖⊖ VERY LOW^{1,2,3},4 due to risk of bias, indirectness, imprecision, publication bias 	156	186	-		The mean targeted behaviour that challenges (severity) – follow-up in the intervention groups was 0.13 standard deviations lower (0.34 lower to 0.08 higher)

Quality as	ssessm	ent					Summ	ary of fir	ndings		
Targeted	behavio	our that challe	nges (severit	y, non-impro	ovement) – po	ost-treatment					
428 (8 studies)	serio us¹	no serious inconsisten cy	no serious indirectnes s	no serious imprecisio n	undetected	$\oplus \oplus \oplus \ominus$ MODERATE ¹ due to risk of bias	174/1 97 (88.3 %)	131/2 31 (56.7 %)	RR 0.67 (0.59 to 0.77)	883 per 1000	291 fewer per 1000 (from 203 fewer to 362 fewer)
Targeted	behavio	our that challe	nges (freque	ncy) – post-t	treatment (Be	tter indicated by lov	wer valu	es)			
633 (9 studies)	serio us ¹	serious ⁵	no serious indirectnes s	no serious imprecisio n	undetected	$\oplus \oplus \ominus \ominus$ LOW ^{1,5} due to risk of bias, inconsistency	294	339	-		The mean targeted behaviour that challenges (frequency) – post- treatment in the intervention groups was 0.54 standard deviations lower (0.8 to 0.28 lower)
Targeted	behavio	our that challe	nges (freque	ncy) – follov	v-up (Better in	dicated by lower va	alues)				
258 (12 studies) 26 weeks	serio us ⁶	no serious inconsisten cy	no serious indirectnes s	serious ⁷	reporting bias strongly suspected ⁴	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{4,6,7} due to risk of bias, imprecision, publication bias	123	135	-		The mean targeted behaviour that challenges (frequency) – follow-up in the intervention groups was 0.23 standard deviations lower (0.47 lower to 0.02 higher)
Targeted	behavio	our that challe	nges (freque	ncy, non-im	provement) –	post-treatment					
343 (6 studies)	serio us¹	no serious inconsisten cy	serious ²	no serious imprecisio n	undetected	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, indirectness	147/1 55 (94.8 %)	105/1 88 (55.9 %)	RR 0.63 (0.55 to 0.73)	948 per 1000	351 fewer per 1000 (from 256 fewer to 427 fewer)
Adaptive	function	ning (commun	nication) – po	st-treatment	(Better indica	ated by higher valu	es)				
124 (1 study)	serio us ⁶	no serious inconsisten	serious ²	very serious ⁷	undetected	⊕⊖⊖⊖ VERY LOW ^{2,6,7}	49	75	-		The mean adaptive functioning

Quality a	issessm	ent					Summ	ary of fir	ndings	
		су				due to risk of bias, indirectness, imprecision				(communication) – post- treatment in the intervention groups was 0.47 standard deviations higher (0.11 to 0.84 higher)
Adaptive	functio	ning (total) – p	oost-treatmer	nt (Better inc	dicated by hig	her values)				
135 (2 studies)	serio us ¹	no serious inconsisten cy	serious ²	serious ³	undetected	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	53	82	-	The mean adaptive functioning (total) – post- treatment in the intervention groups was 0.51 standard deviations higher (0.15 to 0.86 higher)
2 Concer	ns with a	n is from studie pplicability – di tion size not me	fferent popula							

4 Publication bias strongly suspected ${}^{5}l^{2} > 40\%$

⁶ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
 ⁷ Optimal information size not met; small, single study

A.6.2 Individual parent training versus group parent training

Table 0.22: Individual parent training versus group parent training

Quality as	ssessme	ent					Summar	y of finding	S		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study ev (%)	ent rates	Relativ e	Anticipate	ed absolute effects
(studies) Follow up	bias					evidence	With group parent training	With individual parent training	effect (95% CI)	Risk with group parent training	Risk difference with individual parent training (95% CI)
Targeted	behavio	our that challer	nges (severity	/) – post-tr	eatment (Be	etter indicated	d by lower	values)			
38 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2} due to risk of bias, imprecision	15	23	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.38 standard deviations lower (1.04 lower to 0.28 higher)
Targeted	behavio	our that challen	nges (severity	/) – follow-	up (Better i	ndicated by lo	ower value	es)			
38 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕ ⊖ ⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	15	23	-		The mean targeted behaviour that challenges (severity) – follow-up in the intervention groups was 0.05 standard deviations lower (0.7 lower to 0.61 higher)
Targeted	behavio	our that challen	nges (frequen	cy) – post-	treatment (Better indicat	ed by low	er values)			
31 (1 study)	serio us¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	⊕⊖⊝⊖ VERY LOW ^{1,2} due to risk	13	18	-		The mean targeted behaviour that challenges (frequency) – post-treatment in the intervention groups

Quality a	ssessm	ent					Summa	ry of finding	js			
						of bias, imprecision					was 0.34 standard deviations lower (1.06 lower to 0.38 higher)	
Targeted	behavio	our that challen	nges (frequen	cy) – follov	w-up (Bette	r indicated by	v lower va	lues)				
31 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \bigcirc \bigcirc \bigcirc \\ VERY \\ LOW^{1,2} \\ due \text{ to risk} \\ of bias, \\ imprecision \end{array}$	13	18	-		The mean targeted behaviour that challenges (frequency) – follow-up in the intervention groups was 0.12 standard deviations higher (0.59 lower to 0.84 higher)	
	¹ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect ² Optimal information size not met; small, single study											

A.6.3 Parent training plus optimism training versus parent training alone

 Table 0.23: Parent training plus optimism training versus parent training alone

Quality as	ssessme	ent					Summar	y of findings			
Participa	Risk				Study event rates (%)		Relativ	Anticipated absolute effects			
nts (studies) Follow up	of bias	У	S	ion	on bias quality of vidence r		With parent training alone	With parent training plus optimism training	e effect (95% CI)	Risk with parent training alone	Risk difference with parent training plus optimism training (95% CI)
Targeted	behavic	our that challer	nges (severity	y) – post-tr	eatment (B	etter indicate	d by lower	r values)			
35 (1 study)	very serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	⊕⊖⊝⊖ VERY LOW ^{1,2} due to risk	17	18	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups

Quality assessment of bias,							Summar	y of findings			
						of bias, imprecision					was 0.8 standard deviations lower (1.49 to 0.11 lower)
Targeted	behavio	our that challer	nges (severity	y, non-imp	rovement) ·	- post-treatme	ent				
35 (1 study)	very serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	11/17 (64.7%)	5/18 (27.8%)	RR 0.43 (0.19 to 0.98)	647 per 1000	369 fewer per 1000 (from 13 fewer to 524 fewer)
Carer sat	isfactio	n – post-treatn	nent (Better in	ndicated by	y higher va	lues)					
35 (1 study)	very serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\oplus \bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	17	18	-		The mean carer satisfaction – post- treatment in the intervention groups was 0.22 standard deviations higher (0.44 lower to 0.89 higher)

² Optimal information size not met; small, single study

A.6.4 Enhanced parent training versus standard parent training

 Table 0.24: Enhanced parent training versus standard parent training

Quality as	ssessmer	nt					Summary	of finding	s		
Participa nts	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study eve (%)	ent rates	Relativ e	Anticipated	absolute effects
(studies) Follow up						evidence	With standar d parent training	With enhance d parent training	effect (95% CI)	Risk with standard parent training	Risk difference with enhanced parent training (95% CI)
Targeted	behaviou	r that challeng	jes (severity)	– post-tre	atment (Be	tter indicated	by lower v	values)			
50 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊖ LOW ¹ due to imprecisio n	26	24	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.06 standard deviations lower (0.62 lower to 0.49 higher)
Targeted	behaviou	r that challeng	ges (severity)	– follow-u	p (Better in	dicated by lo	wer values	5)			
42 (1 study) 52 weeks	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊖⊖ LOW ¹ due to imprecisio n	19	23	-		The mean targeted behaviour that challenges (severity) – follow-up in the intervention groups was 0.56 standard deviations lower (1.18 lower to 0.06 higher)
Targeted	behaviou	r that challeng	jes (severity,	non-impro	ovement) –	post-treatme	nt				
50 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊝ LOW¹ due to imprecisio	10/26 (38.5%)	13/24 (54.2%)	RR 1.41 (0.77 to	385 per 1000	158 more per 1000 (from 88 fewer to 612 more)

Quality as	ssessmer	nt					Summary	y of finding	IS		
						n			2.59)		
Targeted	behaviou	r that challeng	ges (severity,	non-impro	ovement) -	follow-up					
42 (1 study) 52 weeks	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊝ LOW ¹ due to imprecisio n	11/19 (57.9%)	12/23 (52.2%)	RR 0.9 (0.52 to 1.56)	579 per 1000	58 fewer per 1000 (from 278 fewer to 324 more)
Targeted	behaviou	r that challeng	ges (frequend	cy) – post-f	treatment (I	Better indicat	ed by lowe	er values)			
50 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊖⊖ LOW ¹ due to imprecisio n	26	24	-		The mean targeted behaviour that challenges (frequency) – post- treatment in the intervention groups was 0.04 standard deviations higher (0.52 lower to 0.59 higher)
Targeted	behaviou	r that challeng	ges (frequend	;y) – follow	/-up (Better	indicated by	lower valu	ues)			
42 (1 study) 52 weeks	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊖⊖ LOW ¹ due to imprecisio n	19	23	-		The mean targeted behaviour that challenges (frequency) – follow-up in the intervention groups was 0.04 standard deviations higher (0.56 lower to 0.65 higher)
Targeted	behaviou	r that challeng	ges (frequend	y, non-im	provement)	- post-treatr	nent				
50 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊝ LOW ¹ due to imprecisio n	11/26 (42.3%)	8/24 (33.3%)	RR 0.79 (0.38 to 1.62)	423 per 1000	89 fewer per 1000 (from 262 fewer to 262 more)
Targeted	behaviou	r that challeng	ges (frequenc	y, non-im	provement)	- follow-up					
42	no	no serious	no serious	very	undetect	$\oplus \oplus \ominus \ominus$	4/19	8/23	RR	211 per	137 more per 1000

Quality as	ssessmer	nt					Summary of findings						
(1 study) 52 weeks	serious risk of bias	inconsistenc y	indirectnes s	serious ¹	ed	LOW ¹ due to imprecisio n	(21.1%)	(34.8%)	1.65 (0.59 to 4.65)	1000	(from 86 fewer to 768 more)		
Carer sat	Carer satisfaction- post-treatment (Better indicated by higher values)												
50 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊖⊖ LOW ¹ due to imprecisio n	26	24	-		The mean carer satisfaction- post-treatment in the intervention groups was 0.18 standard deviations higher (0.38 lower to 0.74 higher)		

¹ Optimal information size not met; small, single study

A.7 Psychosocial interventions aimed at reducing and managing behaviour that challenges

A.7.1 Cognitive behavioural interventions versus any control

 Table 0.25: Cognitive behaviour interventions versus any control

ssessmen	t					Summary of findings				
Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study event rates (%)		Relativ e	Anticipa	ated absolute effects
					evidence	With any contr ol	With cognitive behavioural interventions	effect (95% CI)	Risk with any contr ol	Risk difference with cognitive behavioural interventions (95% CI)
behaviou	r that challeng	es (severity)	– post-trea	atment (mea	asured with: Fa	mily ca	rer rated; Bette	r indicate	ed by lov	wer values)
no serious	no serious inconsistenc	no serious indirectnes	very	undetect	$\oplus \oplus \ominus \ominus$ LOW ¹	58	45	-		The mean targeted behaviour that challenges
	Risk of bias behaviou no	bias y behaviour that challeng no no serious	Risk of biasInconsistenc yIndirectnes sbiasyybehaviour that challenges (severity) nono serious	Risk of biasInconsistenc yIndirectnes sImprecis ionbiasyssbehaviour that challenges (severity) – post-treat nono seriousno serious	Risk of bias Inconsistenc y Indirectnes s Imprecis ion Publicati on bias behaviour that challenges (severity) – post-treatment (means on bias) no no serious no serious very undetect	Risk of biasInconsistenc yIndirectnes sImprecis ionPublicati on biasOverall quality of evidencebehaviour that challenges (severity) – post-treatment (measured with: Fa nono seriousno seriousveryundetect $\oplus \oplus \odot \odot$	Risk of biasInconsistenc yIndirectnes sImprecis ionPublicati on biasOverall quality of evidenceStudy (%)With any contr olbehaviour that challenges (severity) – post-treatment (measured with: Family can no no serious no serious very undetect	Risk of bias Inconsistenc y Indirectnes s Imprecis ion Publicati on bias Overall quality of evidence Study event rates (%) With any cognitive behavioural interventions Study event rates With cognitive behavioural interventions behaviour that challenges (severity) – post-treatment (measured with: Family care rated; Better no no serious no serious very undetect Imprecis on bias Study event rates 45	Risk of bias Inconsistenc y Indirectnes s Imprecis ion Publicati on bias Overall quality of evidence Study event rates (%) Relative e effect (95% CI) With any contr ol With cognitive behavioural interventions With cognitive behavioural interventions Post-treatment (measured with: Family carer rated; Better indicate rate) Relative e effect (95% CI) behaviour that challenges (severity) – post-treatment (measured with: Family carer rated; Better indicate rate) no no serious no serious very undetect Imprecise (100 minute) 58 45 -	Risk of bias Inconsistenc y Indirectnes s Imprecis ion Publicati on bias Overall quality of evidence Study event rates (%) Relative effect (95% CI) Anticipation of the properties of the properiment of the properiment of the properties of the properties of t

Quality as	ssessmen	t					Summ	nary of finding	s		
(1 study)	risk of bias	У	S	serious ¹	ed	due to imprecision					(severity) – post-treatment in the intervention groups was 0.24 standard deviations lower (0.63 lower to 0.15 higher)
Targeted	behaviou	r that challeng	es (severity)	– follow-uj	o (measure	d with: Family o	arer rat	ted; Better ind	icated by	lower va	alues)
83 (1 study) 31 weeks	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊖ LOW ¹ due to imprecision	41	42	-		The mean targeted behaviour that challenges (severity) – follow-up in the intervention groups was 0.03 standard deviations lower (0.46 lower to 0.4 higher)
Targeted	behaviou	r that challeng	es (severity,	non-impro	vement) – p	oost-treatment (assess	ed with: Paid o	carer rate	d)	
38 (1 study)	serious 2	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	15/2 0 (75%)	9/18 (50%)	RR 0.67 (0.39 to 1.13)	750 per 1000	247 fewer per 1000 (from 458 fewer to 97 more)
Targeted	behaviou	r that challeng	es (severity)	– post-trea	tment (mea	asured with: Pa	id carer	rated; Better	indicated	by lowe	er values)
194 (2 studies)	no serious risk of bias	serious ³	no serious indirectnes s	serious ⁴	undetect ed	⊕⊕⊖⊖ LOW ^{3,4} due to inconsistency , imprecision	102	92	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.03 standard deviations lower (0.48 lower to 0.42 higher)
Targeted	behaviou	r that challeng	es (severity)	– follow-uj	o (measure	d with: Paid car	er rateo	l; Better indica	ated by Ic	wer valu	ies)
176	no	serious ³	no serious	serious ⁴	undetect	$\oplus \oplus \ominus \ominus$	86	90	-		The mean targeted

Quality as	ssessmen	it					Summ	nary of finding	IS	
(2 studies) 17- 31 weeks	serious risk of bias		indirectnes s		ed	LOW ^{3,4} due to inconsistency , imprecision				behaviour that challenges (severity) – follow-up in the intervention groups was 0.13 standard deviations lower (0.58 lower to 0.33 higher)
Adaptive	functioni	ng – post-treat	ment (measu	red with: F	Paid carer r	ated; Better ind	icated b	oy higher valu	es)	
28 (1 study)	serious 2	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	$\oplus \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	10	18	-	The mean adaptive functioning – post- treatment in the intervention groups was 1.32 standard deviations higher (0.46 to 2.18 higher)
Quality of	f life – pos	st-treatment (m	neasured with	n: Self rate	d; Better in	dicated by high	er valu	es)		
129 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊖⊖ LOW ¹ due to imprecision	67	62	-	The mean quality of life – post-treatment in the intervention groups was 0.16 standard deviations lower (0.5 lower to 0.19 higher)
Quality of	f life – foll	ow-up (measu	red with: Sel	f rated; Be	tter indicate	ed by lower valu	ues)			
140 (1 study) 31 weeks	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ¹	undetect ed	⊕⊕⊝⊖ LOW ¹ due to imprecision	70	70	-	The mean quality of life – follow-up in the intervention groups was 0.02 standard deviations lower (0.35 lower to 0.32 higher)

² Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect 3 l² > 40%

⁴ Optimal information size not met

A.7.2 Behavioural therapy versus any control

Table O.26: Behavioural therapy versus any control

Quality as	ssessme	ent					Summ	ary of findi	ngs		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study (%)	event rates	Relativ e	Anticipa	ted absolute effects
(studies) Follow up	bias					evidence	With Any contr ol	With Behaviou ral therapy	effect (95% CI)	Risk with Any control	Risk difference with Behavioural therapy (95% CI)
Targeted	behavio	our that challen	iges (severity) – post-tre	atment (Be	tter indicated	by lowe	r values)			
61 (1 study)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	30	31	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.47 standard deviations lower (0.98 lower to 0.04 higher)
Targeted	behavio	our that challen	iges (severity) – follow-u	up (Better in	ndicated by lov	wer valu	ies)			
63 (1 study) 78 weeks	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \ominus \ominus \\ VERY \\ LOW^{1,2} \\ due to risk \\ of bias, \\ imprecision \end{array}$	30	33	-		The mean targeted behaviour that challenges (severity) – follow-up in the intervention groups was 0.33 standard deviations lower (0.85 lower to 0.19 higher)

² Optimal information size not met; small, single study

A.8 Sleep interventions aimed at reducing and managing behaviour that challenges

A.8.1 Sleep interventions versus any control

 Table 0.27: Sleep interventions versus any control

Quality as	ssessme	ent					Summ	ary of findir	ngs		
Participa nts	Risk of	Inconsisten cy	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	Study e (%)	event rates	Relativ e	Anticip	ated absolute effects
(studies) Follow up	bias						With any contr ol	With sleep interventi ons	effect (95% CI)	Risk with any contr ol	Risk difference with sleep interventions (95% CI)
Targeted	behavio	our that challer	nges (global	problem sl	eep behavi	our, non-improve	ment) –	post-treatm	nent		
69 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	21/34 (61.8 %)	5/35 (14.3%)	RR 0.23 (0.1 to 0.54)	618 per 1000	476 fewer per 1000 (from 284 fewer to 556 fewer)
Targeted	behavio	our that challer	nges (global	problem sl	eep behavi	our) – post-treatn	nent (Be	tter indicate	ed by low	er value	es)
154 (4 studies)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	serious ⁵	undetect ed	 ⊕⊕⊖⊖ LOW^{4,5} due to risk of bias, imprecision 	77	77	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.05 standard deviations lower (1.48 to 0.63 lower)
Targeted	behavio	our that challer	nges (global	problem sl	eep behavi	our) – follow-up (Better ir	dicated by	lower va	lues)	
130	serio	serious ⁶	no serious	serious ⁵	undetect	$\oplus \Theta \Theta \Theta$	55	75	-		The mean targeted behaviour

Quality as	ssessme	ent					Summa	ary of findir	igs	
(3 studies) 6 to 26 weeks	US ⁴		indirectnes s		ed	VERY LOW ^{4,5,6} due to risk of bias, inconsistency, imprecision				that challenges (global problem sleep behaviour) – follow-up in the intervention groups was 0.92 standard deviations lower (1.6 to 0.24 lower)
Targeted	behavio	our that challer	nges (total sl	eep time) -	- post-treat	ment (measured v	with: Act	igraph; Bet	ter indica	ated by higher values)
96 (2 studies)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	serious ⁵	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{4,5} due to risk of bias, imprecision	48	48	-	The mean targeted behaviour that challenges (total sleep time) – post-treatment in the intervention groups was 0.62 standard deviations higher (0.2 to 1.03 higher)
Targeted	behavio	our that challer	nges (sleep e	efficiency) ·	 post-treat 	ment (measured	with: Ac	tigraph; Be	ter indic	ated by higher values)
96 (2 studies)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	serious ⁵	undetect ed	 ⊕⊕⊖ LOW^{4,5} due to risk of bias, imprecision 	48	48	_	The mean targeted behaviour that challenges (sleep efficiency) – post-treatment in the intervention groups was 0.24 standard deviations higher (0.26 lower to 0.74 higher)
Targeted	behavio	our that challer	nges (total sl	eep time) -	- follow-up	(measured with: A	Actigrap	h; Better in	dicated b	y higher values)
46 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,3} due to risk of bias, imprecision	23	23	-	The mean targeted behaviour that challenges (total sleep time) – follow-up in the intervention groups was 0.14 standard deviations higher (0.44 lower to 0.71 higher)

Quality as	ssessme	ent					Summa	ary of findi	ngs	
Targeted	behavio	our that challer	nges (sleep e	fficiency)	– follow-up	(measured with:	Actigrap	h; Better in	ndicated b	y lower values)
46 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,3} due to risk of bias, imprecision	23	23	-	The mean targeted behaviour that challenges (sleep efficiency) – follow-up in the intervention groups was 0.11 standard deviations lower (0.69 lower to 0.46 higher)
Targeted	behavio	our that challer	nges (sleep o	nset laten	cy) – post-t	reatment (measu	red with:	Actigraph	; Better in	dicated by lower values)
69 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	34	35	-	The mean targeted behaviour that challenges (sleep onset latency) – post-treatment in the intervention groups was 0.59 standard deviations lower (1.07 to 0.11 lower)
Targeted	behavio	our that challer	nges (wake a	fter sleep	onset) – po	st-treatment (mea	sured w	ith: Actigra	ph; Bette	r indicated by lower values)
96 (2 studies)	serio us ⁴	serious ⁶	no serious indirectnes s	serious ⁵	undetect ed	⊕⊖⊖⊖ VERY LOW ^{4,5,6} due to risk of bias, inconsistency, imprecision	48	48	-	The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was 0.31 standard deviations lower (1.13 lower to 0.51 higher)
Targeted	behavio	our that challer	nges (wake a	fter sleep	onset) – fol	low-up (measured	d with: A	ctigraph; E	Setter indi	cated by lower values)
46 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\oplus \Theta \Theta \Theta$ VERY LOW ^{1,3} due to risk of bias, imprecision	23	23	-	The mean targeted behaviour that challenges (wake after sleep onset) – follow-up in the intervention groups was 0.29 standard deviations higher (0.29 lower to 0.88 higher)

Quality a	ssessm	ent					Summ	ary of find	ings		
Targeted	behavio	our that challe	nges (total sl	eep time)	post-treatm	ent (measured w	ith: Slee	p diary; Be	tter indic	ated by	higher values)
30 (1 study)	serio us¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\oplus \bigcirc \bigcirc$ VERY LOW ^{1,3} due to risk of bias, imprecision	15	15	-		The mean targeted behaviour that challenges (total sleep time) post-treatment in the intervention groups was 0.3 standard deviations lower (1.02 lower to 0.42 higher)
Targeted	behavio	our that challer	nges (activity	v score) – I	oost-treatm	ent (measured w	ith: Slee	p diary; Be	tter indica	ated by I	ower values)
30 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,3} due to risk of bias, imprecision	15	15	-		The mean targeted behaviour that challenges (activity score) – post-treatment in the intervention groups was 0.28 standard deviations higher (0.44 lower to 1 higher)
Carer Sat	tisfactio	n (non-satisfie	d) – post-trea	atment							
30 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\oplus \bigcirc \bigcirc$ VERY LOW ^{1,3} due to risk of bias, imprecision	2/17 (11.8 %)	1/13 (7.7%)	RR 0.65 (0.07 to 6.45)	118 per 1000	41 fewer per 1000 (from 109 fewer to 641 more)
² Applicate ³ Optimal ⁴ Most infe	oility- diffe informat ormation	for one criterio erent population ion size not me is from studies	ns t; small, single at moderate	e study	·	eria sufficient to lo	wer ones	confidence	in the est	imate of	effect

⁵ Optimal information size not met 6 l² > 40%

A.8.2 Face-to-face sleep intervention versus booklet only

Table 0.28: Face-to-face slee	p intervention versus booklet only

Quality as	ssessmo	ent					Summ	ary of finding	gs		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study (%)	event rates	Relativ e	Anticipa	ted absolute effects
(studies) Follow up	bias					evidence	With bookl et only	With face- to-face sleep interventio n	effect (95% CI)	Risk with bookle t only	Risk difference with face-to- face sleep intervention (95% CI)
Targeted	behavio	our that challer	iges (global j	oroblem sl	eep behavi	our) – follow-i	up (Bett	er indicated b	by lower v	alues)	
42 (1 study) 26 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	22	20	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – follow-up in the intervention groups was 0.07 standard deviations lower (0.68 lower to 0.53 higher)

² Optimal information size not met; small, single study

A.9 Pharmacological interventions aimed at reducing and managing behaviour that challenges

A.9.1 Risperidone versus placebo in children and young people

 Table 0.29: Risperidone versus placebo in children and young people

Quality as	ssessm	ent					Summ	ary of find	dings		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecisio n	Publicati on bias	Overall quality of evidence	Study of rates (Relativ e	Anticipa	ated absolute effects
(studies) Follow up	bias						With place bo	With risperid one	effect (95% CI)	Risk with place bo	Risk difference with risperidone (95% CI)
Targeted	behavio	our that challer	nges (severity	/) – post-trea	tment (mea	sured with: End-p	oint sco	re; Better	indicate	d by low	er values)
257 (4 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, imprecision	141	116	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 1.09 standard deviations lower (1.39 to 0.79 lower)
Targeted	behavio	ur that challenge	es (severity) –	post-treatme	nt (measure	d with: Change scor	e; Bette	r indicated	by lower	values)	
66 (1 study)	serio us ³	no serious inconsistenc y	serious ⁴	very serious ⁵	undetect ed	⊕⊖⊖⊖ VERY LOW ^{3,4,5} due to risk of bias, indirectness, imprecision	35	31	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.98 standard deviations lower (1.49 to 0.47 lower)

Quality a	ssessm	ent					Summ	ary of fin	dings		
Targeted	behavio	our that challer	nges (severity	, non-impro	vement) – p	ost-treatment					
153 (2 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{1,2} due to risk of bias, imprecision	68/80 (85%)	25/73 (34.2%)	RR 0.42 (0.28 to 0.64)	850 per 1000	493 fewer per 1000 (from 306 fewer to 612 fewer)
Adaptive higher va		ning (social) –	post-treatme	nt (measure	d with: Niso	nger Child Behavi	our Rati	ng Form ·	- Social C	Complia	nce ⁶ ; Better indicated by
155 (3 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, imprecision	88	67	-		The mean adaptive functioning (social) – post- treatment in the intervention groups was 0.86 standard deviations higher (0.42 to 1.3 higher)
Adverse	events (elevated prola	ctin, non-occ	urrence) – p	ost-treatme	nt					
228 (2 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{1,2} due to risk of bias, imprecision	119/1 20 (99.2 %)	97/108 (89.8%)	RR 0.91 (0.85 to 0.97)	992 per 1000	89 fewer per 1000 (from 30 fewer to 149 fewer)
Adverse	events (prolactin-relate	ed adverse ev	vent; oligom	enorrhea, n	on-occurrence) – p	oost-trea	atment			
66 (1 study)	serio us ³	no serious inconsistenc y	serious ⁴	very serious⁵	undetect ed	⊕⊖⊖⊖ VERY LOW ^{3,4,5} due to risk of bias, indirectness, imprecision	35/35 (100 %)	30/31 (96.8%)	RR 0.97 (0.89 to 1.05)	1000 per 1000	30 fewer per 1000 (from 110 fewer to 50 more)
Adverse	events (prolactin level	; ng/ml) – pos	st-treatment	(Better indi	cated by lower valu	ues)				
241 (3 studies)	serio us ³	no serious inconsistenc y	serious ⁴	serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{2,3,4} due to risk of	125	116	-		The mean adverse events (prolactin level; ng/ml) – post-treatment in the

Quality a	ssessm	ent					Summ	ary of fin	dings		
						bias, indirectness, imprecision					intervention groups was 3.22 standard deviations higher (1.68 to 4.75 higher)
Adverse	events (weight; kg) – p	ost-treatmen	t (measured	with: Chan	ge score; Better in	dicated	by lower	values)		
282 (3 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \bigcirc \bigcirc$ LOW ^{1,2} due to risk of bias, imprecision	150	132	-		The mean adverse events (weight; kg) – post- treatment in the intervention groups was 0.82 standard deviations higher (0.57 to 1.06 higher)
Adverse	events (weight; kg) – p	ost-treatmen	t (measured	with: Endp	oint score; Better	indicate	d by lowe	er values)		
53 (1 study)	serio us ³	no serious inconsistenc y	serious ⁴	very serious⁵	undetect ed	⊕⊖⊖⊖ VERY LOW ^{3,4,5} due to risk of bias, indirectness, imprecision	28	25	-		The mean adverse events (weight; kg) – post- treatment in the intervention groups was 0.39 standard deviations higher (0.16 lower to 0.93 higher)
Adverse	events (weight gain, n	on-occurrenc	e) – post-trea	atment						
277 (3 studies)	serio us ¹	no serious inconsistenc y	serious ⁴	serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,4} due to risk of bias, indirectness, imprecision	147/1 48 (99.3 %)	115/12 9 (89.1%)	RR 0.91 (0.85 to 0.96)	993 per 1000	89 fewer per 1000 (from 40 fewer to 149 fewer)
Adverse	events (somnolence/se	edation, non-	occurrence)	– post-treat	tment					
550 (6 studies)	serio us¹	serious ⁷	serious ⁴	no serious imprecisio n	undetect ed	$\bigoplus \bigcirc \bigcirc$ VERY LOW ^{1,4,7} due to risk of bias,	249/2 83 (88%)	138/26 7 (51.7%)	RR 0.58 (0.44 to	880 per 1000	370 fewer per 1000 (from 202 fewer to 493 fewer)

Quality a	ssessm	ent					Summ	ary of find	dings		
						inconsistency, indirectness			0.77)		
Adverse	events (seizure, non-o	ccurrence) –	post-treatme	ent						
101 (1 study)	serio us ³	no serious inconsistenc y	no serious indirectnes s	very serious⁵	undetect ed	$\oplus \bigcirc \bigcirc$ VERY LOW ^{3,5} due to risk of bias, imprecision	51/52 (98.1 %)	49/49 (100%)	RR 1.02 (0.97 to 1.08)	981 per 1000	20 more per 1000 (from 29 fewer to 78 more)
Adverse	events (discontinuatio	n due to adv	erse events,	non-occurr	ence) – post-treatn	nent				
340 (4 studies)	serio us¹	no serious inconsistenc y	serious ⁴	no serious imprecisio n ²	undetect ed	⊕⊕⊖⊖ LOW ^{1,2,4} due to risk of bias, indirectness	175/1 78 (98.3 %)	158/16 2 (97.5%)	RR 0.99 (0.96 to 1.03)	983 per 1000	10 fewer per 1000 (from 39 fewer to 29 more)
Adverse	events (discontinuatio	on due other r	easons, non	-occurrence	e) – post-treatment	:				
450 (5 studies)	serio us ¹	serious ⁷	serious ⁴	no serious imprecisio n	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,4,7} due to risk of bias, inconsistency, indirectness	170/2 35 (72.3 %)	190/21 5 (88.4%)	RR 1.19 (1.06 to 1.34)	723 per 1000	137 more per 1000 (from 43 more to 246 more)

² Optimal information size not met
 ³ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

⁴ Applicability – different populations
 ⁵ Optimal information size not met; small, single study
 ⁶ Combined adaptive social and compliant/calm subscales

 $^{7}l^{2} > 40\%$

A.9.2 Withdrawal of risperidone versus continuation of risperidone in children and young people

 Table O.30: Withdrawal of risperidone versus continuation of risperidone in children and young people

Quality as	ssessme	ent					Summary of	findings			
Participa	Risk	Inconsistenc	Indirectn	Imprecis	Publicati	Overall quality	Study event	rates (%)	Relativ	Anticipated ab	solute effects
nts (studies) Follow up	of bias	У	ess	ion	on bias	of evidence	With continuatio n of risperidone	With withdrawal of risperidon e	e effect (95% CI)	Risk with continuation of risperidone	Risk difference with withdrawal of risperidone (95% CI)
Targeted	behavio	our that challen	ges (relaps	se) – post-t	reatment						
32 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	2/16 (12.5%)	10/16 (62.5%)	RR 5 (1.3 to 19.3)	125 per 1000	500 more per 1000 (from 37 more to 1000 more)

¹ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

² Applicability – different populations

³ Optimal information size not met; small, single study

A.9.3 Aripiprazole versus placebo in children and young people

 Table 0.31: Aripiprazole versus placebo in children and young people

Quality a	ssessme	ent					Summ	ary of find	dings		
Participa nts	Risk of	Inconsistenc y	Indirectn ess	Imprecis ion	Publicati on bias	Overall quality of evidence	Study rates (Relativ e	Anticip	ated absolute effects
(studies) Follow up	bias						With place bo	With aripipra zole	effect (95% CI)	Risk with place bo	Risk difference with aripiprazole (95% CI)
Targeted	behavio	our that challer	nges (sever	ity) – post-	-treatment (Better indicated by lo	ower val	ues)			
308 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	98	210	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.64 standard deviations lower (0.91 to 0.36 lower)
Targeted	behavio	our that challer	nges (sever	ity, non-im	provement) – post-treatment					
308 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	74/98 (75.5 %)	100/21 0 (47.6%)	RR 0.65 (0.5 to 0.84)	755 per 1000	264 fewer per 1000 (from 121 fewer to 378 fewer)
Quality o	f life – p	ost-treatment ((Better indi	cated by h	igher value	s)					
243 (2 studies)	serio us¹	very serious ⁴	serious ²	serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} ,4 due to risk of bias, inconsistency, indirectness, imprecision	76	167	-		The mean quality of life – post-treatment in the intervention groups was 0.6 standard deviations higher (0.17 lower to 1.37 higher)

Quality as	ssessm	ent					Summ	ary of find	dings		
Adverse	events (elevated prola	ctin, non-o	ccurrence)	– post-trea	Itment					
313 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	96/10 1 (95%)	211/21 2 (99.5%)	RR 1.05 (0.99 to 1.1)	950 per 1000	48 more per 1000 (from 10 fewer to 95 more)
Adverse	events (weight gain; k	g) – post- ti	reatment (B	Better indic	ated by lower values)					
216 (1 study)	serio us ⁵	no serious inconsistenc y	serious ²	very serious ⁶	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{2,5,6} due to risk of bias, indirectness, imprecision	51	165	-		The mean adverse events (weight gain; kg) – post- treatment in the intervention groups was 0.48 standard deviations higher (0.17 to 0.8 higher)
Adverse	events (weight gain; cl	linically sig	., non-occ	urrence)						
313 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	94/10 1 (93.1 %)	156/21 2 (73.6%)	RR 0.79 (0.71 to 0.88)	931 per 1000	195 fewer per 1000 (from 112 fewer to 270 fewer)
Adverse	events (sedation, non-	occurrence	e) – post-tr	eatment						
313 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	 ⊕⊖⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	96/10 1 (95%)	165/21 2 (77.8%)	RR 0.83 (0.76 to 0.91)	950 per 1000	162 fewer per 1000 (from 86 fewer to 228 fewer)
Adverse	events (seizure, non-o	ccurrence)	- post-trea	atment						
216 (1 study)	serio us⁵	no serious inconsistenc y	serious ²	very serious ⁶	undetect ed	 ⊕⊖⊖⊖ VERY LOW^{2,5,6} due to risk of bias, indirectness, imprecision 	50/51 (98%)	165/16 5 (100%)	RR 1.03 (0.98 to 1.08)	980 per 1000	29 more per 1000 (from 20 fewer to 78 more)

Quality a	ssessm	ent					Summ	ary of find	dings		
Adverse	events (discontinuatio	n due to ac	lverse eve	nts, non-oc	currence) – post-trea	tment				
316 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	$\oplus \bigcirc \bigcirc$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	96/10 3 (93.2 %)	191/21 3 (89.7%)	RR 0.96 (0.89 to 1.04)	932 per 1000	37 fewer per 1000 (from 103 fewer to 37 more)
Adverse	events (discontinuatio	n due to ot	her reason	ns, non-occ	urrence) – post-treatr	nent				
316 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	81/10 3 (78.6 %)	201/21 3 (94.4%)	RR 1.19 (1.07 to 1.33)	786 per 1000	149 more per 1000 (from 55 more to 260 more)
² Applicat ³ Optimal ⁴ I ² > 75% ⁵ Crucial I	 Most information is from studies at moderate risk of bias Applicability – different populations Optimal information size not met 4 I² > 75% ⁵ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect. Optimal information size not met; small, single study 										

A.9.4 Aripiprazole versus risperidone in children and young people

 Table 0.32: Aripiprazole versus risperidone in children and young people

Quality as	Quality assessment								Summary of findings					
Participa nts	Risk of	Inconsistenc y	Indirectn ess			ent rates	Relativ e	Anticipated absolute effects						
(studies) Follow up	bias						With Risperi done	With Aripipra zole	effect (95% CI)	Risk with Risperid one	Risk difference with Aripiprazole (95% CI)			
Targeted	Targeted behaviour that challenges (severity) – post-treatment (Better indicated by lower values)													
59 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	30	29	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.38 standard deviations higher (0.14 lower to 0.9 higher)			
Adverse	events (drowsiness, no	on-occurre	nce) – pos	t-treatment									
59 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	25/30 (83.3%)	23/29 (79.3%)	RR 0.95 (0.74 to 1.22)	833 per 1000	42 fewer per 1000 (from 217 fewer to 183 more)			
Adverse	events (seizure, non-o	ccurrence)	– post-trea	atment									
59 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	29/30 (96.7%)	29/29 (100%)	RR 1.03 (0.94 to 1.13)	967 per 1000	29 more per 1000 (from 58 fewer to 126 more)			

Adverse events (discontinuation due to adverse events, non-occurrence) – post-treatment59 (1 study)serio us1no serious inconsistenc yserious2very serious3undetect ed $\bigoplus \bigcirc (VERY LOW^{1,2,3})$ due to risk of bias, indirectness, imprecision29/30 (96.7%)29/29 (100%)RR 1.03 (0.94 to 1.13)967 per 100029 more per 1000 (from 58 fewer to 126 more)Adverse events (discontinuation due to other reasons, non-occurrence) – post-treatment59 (1 study)serio us1no serious prosistenc yserious2very serious2undetect ed $\bigoplus \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc \bigcirc (VERY LOW^{1,2,3})$ due to risk of bias, indirectness, imprecision28/30 (93.3%)27/29 (93.1%)RR 1 (0.87 to 1.14)933 per 1000 (from 121 fewer to 131 more)59 (1 study)us1no serious py serious2very serious3undetect ed $\oplus \bigcirc \bigcirc \bigcirc \bigcirc \\ VERY LOW^{1,2,3} \\ due to risk of bias, indirectness, imprecision28/30(93.3%)27/29(93.1%)RR 1(0.87to1.14)933 per1000(from 121 fewer to 131more)$	Quality assessment								Summary of findings					
$ \begin{array}{c} (1 \text{ study}) \\ (1 \text{ study}) \\ us^{1} \\ study \\ study \\ us^{1} \\ study \\ $	Adverse	Adverse events (discontinuation due to adverse events, non-occurrence) – post-treatment												
59 (1 study)serious us1no serious inconsistenc yserious2very serious3undetect ed $\bigoplus \ominus \ominus \ominus$ VERY LOW1,2,3 due to risk of bias, indirectness,28/30 (93.3%)27/29 (93.1%)RR 1 (0.87 to 1.14)933 per 10000 fewer per 1000 (from 121 fewer to 131 more)				serious ²	,		VERY LOW ^{1,2,3} due to risk of bias, indirectness,			1.03 (0.94 to	•	•		
(1 study) us ¹ inconsistenc y serious ³ ed VERY LOW ^{1,2,3} (93.3%) (93.1%) (0.87 1000 (from 121 fewer to 131 due to risk of bias, indirectness,	Adverse	events (discontinuatio	n due to ot	her reason	ns, non-occ	urrence) – post-ti	reatment						
			inconsistenc	serious ²	,		VERY LOW ^{1,2,3} due to risk of bias, indirectness,			(0.87 to		(from 121 fewer to 131		

² Applicability – different populations
 ³ Optimal information size not met; small, single study

A.9.5 Withdrawal of aripiprazole versus continuation of aripiprazole in children and young people

 Table 0.33: Withdrawal of aripiprazole versus continuation of aripiprazole in children and young people

Quality as	ssessme	ent			Summary of findings							
Participa	Risk	Inconsistenc	Indirectn	Imprecis ion	Publicati	Overall quality	Study event rates (%)		Relativ	Anticipated absolute effects		
nts (studies) Follow up	of bias	У	ess		on bias	of evidence	With continuatio n of aripiprazole	With withdrawal of aripiprazol e	e effect (95% CI)	Risk with continuation of aripiprazole	Risk difference with withdrawal of aripiprazole (95% CI)	
Targeted	Targeted behaviour that challenges (relapse) – post-treatment											
85 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	14/41 (34.1%)	23/44 (52.3%)	RR 1.53 (0.92 to 2.55)	341 per 1000	181 more per 1000 (from 27 fewer to 529 more)	
Adverse	events (v	weight gain; cl	inically sig	., non-occı	urrence)							
85 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	39/41 (95.1%)	43/44 (97.7%)	RR 1.03 (0.95 to 1.12)	951 per 1000	29 more per 1000 (from 48 fewer to 114 more)	
Adverse	events (discontinuatio	n due to ad	verse ever	nts, non-oco	currence) – post-t	reatment					
85 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	41/41 (100%)	43/44 (97.7%)	RR 0.98 (0.92 to 1.04)	1000 per 1000	20 fewer per 1000 (from 80 fewer to 40 more)	

Quality as	ssessme	ent			Summary of findings							
Adverse	Adverse events (discontinuation due to other reasons, non-occurrence) – post-treatment											
85 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \bigcirc \bigcirc$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	22/41 (53.7%)	20/44 (45.5%)	RR 0.85 (0.55 to 1.3)	537 per 1000	80 fewer per 1000 (from 241 fewer to 161 more)	
² Applicab	¹ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect ² Applicability – different populations ³ Optimal information size not met; small, single study											

A.9.6 Olanzapine versus haloperidol in children and young people

Table 0.34: Olanzapine versus haloperidol in children and young people

Quality assessment								Summary of findings					
Participa nts	Risk of		Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study event rates (%)		s Relativ e effect	Anticipated absolute effects			
(studies) Follow up	bias					evidence	With haloper idol	With olanza pine	(95% CI)	Risk with haloperi dol	Risk difference with olanzapine (95% CI)		
Targeted	Targeted behaviour that challenges (severity) – post-treatment (Better indicated by lower values)												
12 (1 study)	very seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	6	6	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 1.4 standard deviations lower (2.73 to 0.08 lower)		
Adverse events (drowsiness, non-occurrence) – post-treatment													
12	very	no serious	no serious	very	undetect	$\oplus \Theta \Theta \Theta$	4/6	1/6	RR	667 per	500 fewer per 1000		

	seriou s ¹	inconsistenc y	indirectnes s	serious ²	ed	VERY LOW ^{1,2} due to risk of bias, imprecision	(66.7%)	(16.7%)	0.25 (0.04 to 1.63)	1000	(from 640 fewer to 420 more)
Adverse ev	vents –	(weight gain; k	(g) – post-trea	atment (Bet	ter indicate	d by lower va	lues)				
(1 study)	very seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	6	6	-		The mean adverse events – (weight gain; kg) – post- treatment in the intervention groups was 1.26 standard deviations higher (0.03 lower to 2.54 higher)
Adverse ev	vents (w	veight gain) – p	oost-treatmen	t							
(1 study)	very seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	6/6 (100%)	5/6 (83.3%)	RR 0.85 (0.55 to 1.31)	1000 per 1000	150 fewer per 1000 (from 450 fewer to 310 more)

² Optimal information size not met; small, single study

A.9.7 Topiramate (plus risperidone) versus placebo (plus risperidone) in children and young people

 Table 0.35: Topiramate (plus risperidone) versus placebo (plus risperidone) in children and young people

Quality as	ssessmei	nt					Summary	of findings			
Participa	Risk of	Inconsisten	Indirectn	Imprecis	Publicati	Overall	Study ever	nt rates (%)	Relativ	Anticipated	absolute effects
nts (studies) Follow up	bias	су	ess	ion	on bias	quality of evidence	With placebo plus risperido ne	With topiramat e plus risperidon e	e effect (95% CI)	Risk with Placebo plus risperidon e	Risk difference with topiramate plus risperidone (95% CI)
Targeted	behaviou	ur that challeng	ges (severi	ty) – post-f	reatment (I	Better indicate	d by lower	values)			
40 (1 study)	no seriou s risk of bias	no serious inconsistenc y	serious ¹	very serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2} due to indirectness , imprecision	20	20	-		The mean targeted behaviour that challenges (severity) – post- treatment in the intervention groups was 1.88 standard deviations lower (2.63 to 1.12 lower)
Adverse e	events (s	edation, non-o	occurrence) – post-tre	atment						
40 (1 study)	no seriou s risk of bias	no serious inconsistenc y	serious ¹	very serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2} due to indirectness , imprecision	16/20 (80%)	19/20 (95%)	RR 1.19 (0.93 to 1.51)	800 per 1000	152 more per 1000 (from 56 fewer to 408 more)
Adverse	events (w	eight at endpo	oint; kg) – p	oost-treatm	nent (Better	indicated by	lower values	s)			
40 (1 study)	no seriou s risk of bias	no serious inconsistenc y	serious ¹	very serious ²	undetect ed	⊕⊖⊝⊖ VERY LOW ^{1,2} due to	20	20	-		The mean adverse events (weight at endpoint; kg) – post- treatment in the

Quality assessment	Summary of findings	
	indirectness , imprecision	intervention groups was 0.24 standard deviations lower (0.87 lower to 0.38 higher)
 ¹ Applicability – different populations ² Optimal information size not met; small, single study 		

A.9.8 Valproate versus placebo in children and young people

Table O.36: Topiramate (plus risperidone) versus placebo (plus risperidone) in children and young people

Quality as	ssessme	ent					Summ	ary of fir	ndings		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	Study e rates (9		Relativ e effect	Anticipa	ated absolute effects
(studies) Follow up	bias						With place bo	With valpro ate	(95% CI)	Risk with place bo	Risk difference with valproate (95% CI)
Targeted	behavio	ur that challen	ges (severity)	– post-trea	atment (Bet	ter indicated by low	er value	es)			
57 (2 studies)	seriou s ¹	serious ²	no serious indirectnes s	serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, inconsistency, imprecision 	25	32	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.06 standard deviations lower (0.75 lower to 0.63 higher)
Targeted	behavio	ur that challen	ges (severity,	non-impro	vement) – p	post-treatment					
27 (1 study)	seriou s ⁴	no serious inconsistenc y	no serious indirectnes s	very serious⁵	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{4,5} due to risk of bias, imprecision	10/11 (90.9 %)	6/16 (37.5 %)	RR 0.41 (0.21 to 0.8)	909 per 1000	536 fewer per 1000 (from 182 fewer to 718 fewer)

Adverse e	events (v	veight gain; kg) – post-treatı	nent (meas	sured with:	Change score; Bet	er indic	ated by	lower val	ues)	
57 (2 studies)	seriou S ¹	no serious inconsistenc y	no serious indirectnes s	serious ³	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,3} due to risk of bias, imprecision	25	32	-		The mean adverse events (weight gain; kg) – post- treatment in the intervention groups was 0.29 standard deviations higher (0.24 lower to 0.82 higher)
Adverse e	events (v	veight gain, no	n-occurrence) – post-tre	atment						
30 (1 study)	seriou s ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ⁵	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{4,5} due to risk of bias, imprecision	10/14 (71.4 %)	9/16 (56.3 %)	RR 0.79 (0.46 to 1.36)	714 per 1000	150 fewer per 1000 (from 386 fewer to 257 more)
Adverse e	events (s	somnolence/se	dation, non-o	ccurrence)	– post-trea	tment					
57 (2 studies)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	serious ³	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,3} due to risk of bias, imprecision	19/25 (76%)	29/32 (90.6 %)	RR 1.19 (0.9 to 1.56)	760 per 1000	144 more per 1000 (from 76 fewer to 426 more)
Adverse e	events (c	liscontinuatior	due to adver	se events,	non-occurr	ence) – post-treatn	nent				
57 (2 studies)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	serious ³	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,3} due to risk of bias, imprecision	25/25 (100 %)	30/32 (93.8 %)	RR 0.95 (0.83 to 1.08)	1000 per 1000	50 fewer per 1000 (from 170 fewer to 80 more)
Adverse e	events (c	liscontinuatior	due to other	reasons, n	on-occurre	nce) – post-treatme	ent				
27 (1 study)	seriou s ⁴	no serious inconsistenc y	no serious indirectnes s	very serious⁵	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{4,5} due to risk of bias, imprecision	10/11 (90.9 %)	15/16 (93.8 %)	RR 1.03 (0.82 to 1.29)	909 per 1000	27 more per 1000 (from 164 fewer to 264 more)
1 Most info 2 I ² > 40%	ormation	is from studies	at moderate ris	sk of bias							

³ Optimal information size not met
 ⁴ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect
 ⁵ Optimal information size not met; small, single study

N-acetylcysteine versus placebo in children and young people A.9.9

Table 0.37: N-acetylcysteine versus placebo in children and young people

Quality as	ssessm	ent					Summ	ary of finding	js		
Participa nts	Risk of	Inconsistenc y	Indirectn ess	Imprecis ion	Publicati on bias	Overall quality of evidence	Study (%)	event rates	Relativ e	Anticip	ated absolute effects
(studies) Follow up	bias						With place bo	With N- acetylcyste ine (NAC)	effect (95% CI)	Risk with place bo	Risk difference with N- acetylcysteine (NAC) (95% CI)
Targeted	behavio	our that challer	nges (sever	ity) – post-	-treatment (Better indicated I	oy lower	values)			
29 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	15	14	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.70 standard deviations lower (1.46 lower to 0.05 higher)
Adverse e	events (discontinuatio	n due to ad	lverse evei	nts, non-oc	currence) – post-	treatme	nt			
33 (1 study)	serio us ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	18/18 (100 %)	14/15 (93.3%)	RR 0.93 (0.78 to 1.11)	1000 per 1000	70 fewer per 1000 (from 220 fewer to 110 more)
Adverse e	events (discontinuatio	n due to ot	her reason	s, non-occ	urrence) – post-tr	eatment				
33	serio	no serious	serious ²	very	undetect	$\oplus \ominus \ominus \ominus$	12/18	14/15	RR 1.4	667	267 more per 1000

Quality a	ssessm	ent					Summ	ary of finding	IS		
(1 study)	US ¹	inconsistenc y	seric	ous ³	ed	VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	(66.7 %)	(93.3%)	(0.98 to 1.99)	per 1000	(from 13 fewer to 660 more)
² Applicat	oility – dif	ferent population			multiple cri	teria sufficient to lo	ower one	es confidence i	n the esti	mate of e	offect

A.9.10 Ginkgo biloba (plus risperidone) versus placebo (plus risperidone) in children and young people

Table O.38: Ginkgo biloba (plus risperidone) versus placebo (plus risperidone) in children and young people

Quality as	ssessmei	nt					Summary	of findings			
Participa	Risk of	Inconsisten	Indirectn	Imprecis	Publicati	Overall	Study ever	nt rates (%)	Relativ	Anticipated	absolute effects
nts (studies) Follow up	bias	су	ess	ion	on bias	quality of evidence	With placebo plus risperido ne	With ginkgo biloba plus risperidon e	e effect (95% CI)	Risk with placebo plus risperidon e	Risk difference with ginkgo biloba plus risperidone (95% CI)
Targeted	behaviou	ir that challen	ges (severi	ty) – post-t	reatment (I	Better indicate	ed by lower	values)			
47 (1 study)	no seriou s risk of bias	no serious inconsistenc y	serious ¹	very serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2} due to indirectness , imprecision	24	23	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.1 standard deviations higher (0.47 lower to 0.67 higher)

Quality as	ssessmei	nt					Summary	of findings				
Adverse events (drowsiness, non-occurrence) – post-treatment												
47 (1 study)	47 no no serious serious ¹ very undetect $\oplus \ominus \ominus \ominus$ 17/24 17/23 RR 708 per 28 more per 1000											
	¹ Applicability – different populations ² Optimal information size not met; small, single study											

A.9.11 Omega-3 versus placebo in children and young people

 Table 0.39: Omega-3 versus placebo in children and young people

Quality as	ssessme	ent					Summ	ary of fi	ndings		
Participa nts	Risk of	Inconsistenc y	Indirectn ess	Imprecis ion	Publicati on bias	Overall quality of evidence	Study e rates (*		Relativ e effect	Anticipa	ted absolute effects
(studies) Follow up	bias						With place bo	With omeg a-3	(95% CI)	Risk with place bo	Risk difference with omega-3 (95% CI)
Targeted	behavio	ur that challen	ges (severi	ty) – post-l	treatment (E	Better indicated by	lower v	alues)			
12 (1 study)	seriou S ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	5	7	-		The mean targeted behaviour that challenges (severity) – post- treatment in the intervention groups was 0.37 standard deviations higher (0.79 lower to 1.53 higher)
Adverse e	events (o	discontinuation	due to adv	verse even	ts, non-occ	urrence) – post-tre	eatment				
13	seriou	no serious	serious ²	very	undetect	$\oplus \Theta \Theta \Theta$	5/6	7/7	RR	833	158 more per 1000

Quality as	y due to risk of bias, indirectness,						Summ	ary of fi	indings		
(1 study)	S ¹	inconsistenc y	seri	rious ³	ed	bias,	(83.3 %)	(100 %)	1.19 (0.78 to 1.83)	per 1000	(from 183 fewer to 692 more)
² Applicab	oility – dif	for one criterion of ferent populations ion size not met;	6		multiple crite	eria sufficient to low	er ones	confider	nce in the	estimate	of effect

A.9.12 Piracetam (plus risperidone) versus placebo (plus risperidone) in children and young people

Table O.40: Piracetam (plus risperidone) versus placebo (plus risperidone) in children and young people

Quality as	ssessme	ent					Summary of	f findings			
Participa	Risk	Inconsistenc	Indirectn	Imprecis	Publicati	Overall quality	Study event	rates (%)	Relativ	Anticipated al	osolute effects
nts (studies) Follow up	of bias	У	ess	ion	on bias	of evidence	With placebo (plus risperidone)	With piracetam (plus risperidone)	e effect (95% CI)	Risk with placebo (plus risperidone)	Risk difference with piracetam (plus risperidone) (95% CI)
Adverse e	events (o	drowsiness, no	n-occurren	ce) – post-	treatment						
40 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	11/20 (55%)	13/20 (65%)	RR 1.18 (0.71 to 1.97)	550 per 1000	99 more per 1000 (from 160 fewer to 534 more)

¹ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

² Applicability – different populations

³ Optimal information size not met; small, single study

A.9.13 Risperidone versus placebo in adults

Table 0.41: Risperidone versus placebo in adults

Quality as	ssessmen	t					Summ	ary of find	dings		
Participa nts	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	Study rates (Relativ e	Anticipa	ated absolute effects
(studies) Follow up							With place bo	With risperid one	effect (95% CI)	Risk with place bo	Risk difference with risperidone (95% CI)
Targeted	behaviour	that challenge	es (severity) -	- post-treat	ment (mea	sured with: End-	-point s	core; 12 w	veek; Bett	er indica	ated by lower values)
88 (2 studies)	no serious risk of bias	serious ¹	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to inconsistency, imprecision	45	43	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.25 standard deviations lower (0.94 lower to 0.44 higher)
Targeted	behaviour	that challenge	es (severity) -	- post-treat	ment (meas	sured with: Cha	nge-sco	re; 12 wee	ek; Better	indicate	ed by lower values)
74 (1 study)	serious ³	no serious inconsistenc y	no serious indirectnes s	very serious ⁴	undetect ed	⊕⊖⊖⊖ VERY LOW ^{3,4} due to risk of bias, imprecision	37	37	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.44 standard deviations lower (0.9 lower to 0.02 higher)
Targeted	behaviour	that challenge	es (severity) -	- post-treat	ment (mea	sured with: End	point-sc	ore; 26 w	eeks⁵; Be	tter indi	cated by lower values)
37 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ⁴	undetect ed	⊕⊕⊝⊖ LOW ⁴ due to imprecision	20	17	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.16 standard deviations

Quality as	ssessmen	t					Summ	ary of fin	dings		
											higher (0.48 lower to 0.81 higher)
Quality of	f life – pos	st-treatment (m	easured with	: 12 weeks	; Better ind	icated by higher	values))			
58 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ⁴	undetect ed	⊕⊕⊝⊝ LOW⁴ due to imprecision	29	29	-		The mean quality of life – post-treatment in the intervention groups was 0.27 standard deviations higher (0.25 lower to 0.79 higher)
Quality of	f life – pos	t-treatment (m	easured with	: 26 weeks	^₅ ; Better inc	dicated by highe	r values	5)			
40 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ⁴	undetect ed	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^4 \\ due to \\ imprecision \end{array}$	21	19	-		The mean quality of life – post-treatment in the intervention groups was 0.2 standard deviations higher (0.42 lower to 0.82 higher)
Adaptive	functionir	ng (social) – po	st-treatment	(Better ind	icated by lo	ower values)					
30 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ⁴	undetect ed	⊕⊕⊝⊖ LOW ⁴ due to imprecision	16	14	-		The mean adaptive functioning (social) – post- treatment in the intervention groups was 1.36 standard deviations lower (2.17 to 0.56 lower)
Adverse e	events (we	eight gain, non	-occurrence)	– post-trea	atment						
31 (1 study)	no serious risk of bias	no serious inconsistenc y	serious ⁶	very serious ⁴	undetect ed	 ⊕⊖⊖ VERY LOW^{4,6} due to indirectness, imprecision 	16/16 (100 %)	13/15 (86.7%)	RR 0.87 (0.69 to 1.09)	1000 per 1000	130 fewer per 1000 (from 310 fewer to 90 more)
Adverse	events (so	mnolence/sed	ation, non-oc	currence) ·	 post-treat 	ment					
108 (2	no serious	very serious ⁷	no serious indirectnes	serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{2,7}	48/54 (88.9	36/54 (66.7%	RR 0.65	889 per	311 fewer per 1000 (from 640 fewer to 418 more)

Quality a	ssessmen	t					Summ	ary of fin	dings		
studies)	risk of bias		S			due to inconsistency, imprecision	%))	(0.28 to 1.47)	1000	
Adverse	events (dis	scontinuation	due to advers	e events, r	non-occurre	ence) – post-trea	atment				
89 (2 studies)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ⁴	undetect ed	⊕⊕⊕⊖ MODERATE ⁴ due to imprecision	45/45 (100 %)	41/44 (93.2%)	RR 0.95 (0.87 to 1.04)	1000 per 1000	50 fewer per 1000 (from 130 fewer to 40 more)
Adverse	events (dis	scontinuation	due to other r	easons, no	on-occurrei	nce) – post-treat	ment				
166 (3 studies)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ⁴	undetect ed	⊕⊕⊕⊝ MODERATE ⁴ due to imprecision	67/83 (80.7 %)	70/83 (84.3%)	RR 1.04 (0.92 to 1.18)	807 per 1000	32 more per 1000 (from 65 fewer to 145 more)

 1 I² > 40%

² Optimal information size not met

³ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect

⁴ Optimal information size not met; small, single study ⁵ Participants agreed to take the study drug for 12 weeks, with the option of continuing until 26 weeks, unless at 12 weeks other options were preferred. Post-treatment data is therefore provided at both 12 and 26 week end of treatment.

⁶ Applicability – different populations

 $^{7}l^{2} > 75\%$

A.9.14 Haloperidol versus placebo in adults

Table 0.42: Haloperidol versus placebo in adult	Table 0.42:	Haloperidol versus	placebo in adults
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Quality asse	essment						Summa	ry of findings			
Participants	Risk of	Inconsiste	Indirectne	Imprecisio	Publicatio	Overall	Study ev	vent rates (%)	Relativ	Anticipa	ted absolute effects
(studies) Follow up	bias	ncy	SS	n	n bias	quality of evidence	With placeb o	With haloperidol	e effect (95% CI)	Risk with placeb o	Risk difference with haloperidol (95% CI)
Targeted beh	naviour that o	hallenges (se	everity) – post	-treatment (m	easured with:	12 weeks ¹ ; E	Better indic	ated by lower	values)		
57 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	 ⊕⊕⊖⊖ LOW² due to imprecisio n 	29	28	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.48 standard deviations lower (1 lower to 0.05 higher)
Targeted beh	naviour that o	hallenges (se	everity) – post	-treatment (m	easured with:	26 weeks1; E	Better indic	ated by lower	values)		
40 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	⊕⊕⊝⊝ LOW ² due to imprecisio n	20	20	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.25 standard deviations lower (0.87 lower to 0.37 higher)

Quality of life – post-treatment (measured with: 12 weeks¹; Better indicated by higher values)

Quality ass	essment						Summa	ry of findings	5		
57 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	⊕⊕⊝⊝ LOW ² due to imprecisio n	29	28	-		The mean quality of life – post-treatment in the intervention groups was 0.17 standard deviations lower (0.69 lower to 0.35 higher)
Quality of lif	e – post-treat	ment (measu	red with: 26 w	eeks ¹ ; Better	indicated by I	nigher values)					
41 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	⊕⊕⊝⊝ LOW ² due to imprecisio n	21	20	-		The mean quality of life – post-treatment in the intervention groups was 0.18 standard deviations lower (0.79 lower to 0.43 higher)
Adverse eve	ents (seizure,	non-occurren	ice) – post-tre	atment							
57 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	⊕⊕⊝⊝ LOW ² due to imprecisio n	29/29 (100%)	27/28 (96.4%)	RR 0.96 (0.88 to 1.06)	1000 per 1000	40 fewer per 1000 (from 120 fewer to 60 more)
Adverse eve	ents (disconti	nuation due to	adverse ever	nts, non-occu	irrence) – pos	t-treatment					
57 (1 study)	no serious risk of bias	no serious inconsiste ncy	no serious indirectnes s	very serious ²	undetecte d	⊕⊕⊖⊖ LOW ² due to imprecisio n	29/29 (100%)	26/28 (92.9%)	RR 0.93 (0.82 to 1.05)	1000 per 1000	70 fewer per 1000 (from 180 fewer to 50 more)
Adverse eve	ents (disconti	nuation due to	other reason	s, non-occurr	ence) – post-	treatment					
57	no	no serious	no serious	very	undetecte	$\oplus \oplus \ominus \ominus$	21/29	23/28	RR	724	94 more per 1000

Quality asse	essment						Summa	ry of findings			
(1 study)	serious risk of bias	inconsiste ncy	indirectnes s	serious ²	d	LOW ² due to imprecisio n	(72.4%)	(82.1%)	1.13 (0.85 to 1.51)	per 1000	(from 109 fewer to 369 more)
¹ Patients ag	reed to take	the study drug	g for 12 weeks	s, with the opt	tion of continu	uing until 26 w	eeks, unle	ess at 12 week	s other op	tions were	e preferred. Post-

treatment data is therefore provided at both 12 and 26 week end of treatment.

² Optimal information size not met; small, single trial

A.9.15 Risperidone versus haloperidol in adults

Table 0.43: Risperidone versus haloperidol in adults

Quality as	ssessmen	ıt					Summa	y of findi	ngs		
Participa nts	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study ev (%)	ent rates	Relativ e	Anticipate	d absolute effects
(studies) Follow up						evidence	With haloper idol	With risperid one	effect (95% CI)	Risk with haloperi dol	Risk difference with risperidone (95% CI)
Targeted	behaviou	r that challeng	es (severity)	– post-trea	itment (mea	sured with: 1	2 weeks ¹ ;	Better in	dicated b	y lower va	lues)
57 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊕⊖ LOW² due to imprecision 	28	29	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.49 standard deviations higher (0.03 lower to 1.02 higher)
Targeted	behaviou	r that challeng	es (severity)	– post-trea	itment (mea	sured with: 2	6 weeks ¹ ;	Better in	dicated b	y lower va	lues)
36 (1 study)	no serious risk of	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	⊕⊕⊝⊖ LOW ² due to	19	17	-		The mean targeted behaviour that challenges (severity) – post-treatment in the

Quality as	ssessmer	nt					Summa	ry of findi	ngs		
	bias					imprecision					intervention groups was 0.39 standard deviations higher (0.28 lower to 1.05 higher)
Quality of	f life – pos	st-treatment (n	neasured with	n: 12 weeks	s ¹ ; Better in	dicated by high	gher valu	es)			
57 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	⊕⊕⊖⊖ LOW ² due to imprecision	28	29	-		The mean quality of life – post-treatment in the intervention groups was 0.43 standard deviations higher (0.09 lower to 0.96 higher)
Quality of	f life – pos	st-treatment (n	neasured with	n: 26 weeks	s 1; Better i	ndicated by h	igher valu	ues)			
39 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \bigoplus \bigoplus \bigoplus \\ LOW^2 \\ due to \\ imprecision \end{array}$	20	19	-		The mean quality of life – post-treatment in the intervention groups was 0.41 standard deviations higher (0.23 lower to 1.04 higher)
Adverse	events (se	eizure, non-oco	currence) – p	ost-treatme	ent						
57 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \bigoplus \ominus \ominus \\ LOW^2 \\ due to \\ imprecision \end{array}$	27/28 (96.4%)	29/29 (100%)	RR 1.04 (0.94 to 1.14)	964 per 1000	39 more per 1000 (from 58 fewer to 135 more)
Adverse	events (di	scontinuation	due to adver	se events)	– post-trea	tment					
57 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \bigoplus \ominus \ominus \\ LOW^2 \\ due to \\ imprecision \end{array}$	26/28 (92.9%)	28/29 (96.6%)	RR 1.04 (0.92 to 1.18)	929 per 1000	37 more per 1000 (from 74 fewer to 167 more)
Adverse	events (di	scontinuation	due to other	reasons) –	post-treatr	nent					
57	no	no serious	no serious	very	undetect	$\oplus \oplus \ominus \ominus$	24/28	23/29	RR	857 per	60 fewer per 1000

Quality a	risk of y s due to							y of findi	ngs		
(1 study)	risk of	inconsistenc y		serious ²	ed		(85.7%)	(79.3%)	0.93 (0.73 to 1.18)	1000	(from 231 fewer to 154 more)
treatment	data is the	take the study over erefore provided n size not met;	l at both 12 an	d 26 week			l 26 weeks	s, unless a	t 12 week	s other opti	ons were preferred. Post-

A.9.16 Olanzapine versus risperidone in adults

Table 0.44: Olanzapine versus risperidone in adults

Quality as	ssessme	ent					Summar	y of findi	ngs		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study ev (%)	ent rates	Relativ e	Anticipate	d absolute effects
(studies) Follow up	bias					evidence	With risperid one	With olanza pine	effect (95% CI)	Risk with risperido ne	Risk difference with olanzapine (95% CI)
Targeted	behavio	ur that challen	ges (frequend	;y) – post-t	reatment (B	Better indicate	d by lower	values)			
62 (1 study)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	31	31	-		The mean targeted behaviour that challenges (frequency) – post-treatment in the intervention groups was 0.2 standard deviations higher (0.3 lower to 0.7 higher)
Adverse e	events (e	elevated prolac	tin) – post-tre	eatment							
62 (1 study)	seriou s¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2} due to risk	30/31 (96.8%)	22/31 (71%)	RR 0.73 (0.58 to	968 per 1000	261 fewer per 1000 (from 68 fewer to 406 fewer)

						of bias, imprecision			0.93)		
Adverse e	events (v	veight gain, no	n-occurrence	e) – post-tre	eatment						
62 (1 study)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	28/31 (90.3%)	24/31 (77.4%)	RR 0.86 (0.69 to 1.07)	903 per 1000	126 fewer per 1000 (from 280 fewer to 63 more)
Adverse e	events (s	edation, non-c	occurrence) –	post-treat	nent						
62 (1 study)	seriou s ²	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW² due to risk of bias, imprecision 	26/31 (83.9%)	24/31 (77.4%)	RR 0.92 (0.72 to 1.18)	839 per 1000	67 fewer per 1000 (from 235 fewer to 151 more)

² Optimal information size not met; small, single study

A.9.17 Lithium versus placebo in adults

Table 0.45: Lithium versus placebo in adults

Quality as	ssessmer	nt					Summa	ary of fin	dings		
Participa nts	Risk of bias	Inconsistency	Indirectness	Imprecis ion	Publicatio n bias	Overall quality of evidence	Study e rates (%		Relative effect	Anticipate	d absolute effects
(studies) Follow up							With place bo	With lithiu m	(95% CI)	Risk with placebo	Risk difference with lithium (95% CI)
Targeted	behaviou	r that challenges	(frequency, no	n-improver	nent)						
42 (1 study)	serious	no serious inconsistency	no serious indirectness	very serious ²	undetecte d	⊕⊖⊖⊖ VERY LOW ^{1,2}	14/20 (70%)	6/22 (27.3	RR 0.39 (0.19 to	700 per 1000	427 fewer per 1000

Quality assessment	Summary of findings	
	due to risk of bias, imprecision%)0.82)(from 126 feature to 567 fewer	
¹ Crucial limitation for one criterion or some limitations for multiple cri ² Optimal information size not met; small, single study	eria sufficient to lower ones confidence in the estimate of effect	

A.9.18 Withdrawal of zuclopenthixol versus continuation of zuclopenthixol in adults

Table O.46: Withdrawal of zuclopenthixol versus continuation of zuclopenthixol in adults

Quality as	ssessm	ent					Summary of	findings			
Participa	Risk	Inconsisten	Indirectne	Imprecis	Publicati	Overall quality	Study event	rates (%)	Relati	Anticipated al	bsolute effects
nts (studies) Follow up	of bias	су	SS	ion	on bias	of evidence	With continuatio n of zuclopenthi xol	With withdrawal of zuclopenthi xol	ve effect (95% CI)	Risk with continuation of zuclopenthi xol	Risk difference with withdrawal of zuclopenthixol (95% Cl)
Targeted	behavio	our that challe	nges (relaps	e) – post-t	reatment						
39 (1 study)	serio us¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2} due to risk of bias, imprecision	12/19 (63.2%)	19/20 (95%)	RR 1.5 (1.05 to 2.15)	632 per 1000	316 more per 1000 (from 32 more to 726 more)
Targeted	behavio	our that challe	nges (severi	ty) – post-l	treatment (r	neasured with:	End-point sco	ore; Better inc	dicated b	y lower values	s)
39 (1 study)	serio us ¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	19	20	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.56 standard deviations higher

											(0.08 lower to 1.2 higher)
Targeted	behavio	our that challe	nges (severi	ty) – post-f	reatment (r	neasured with:	Change score	e; Better indic	ated by	lower values)	
85 (1 study)	serio us ¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2} due to risk of bias, imprecision	45	40	-		The mean targeted behaviour that challenges (severity) – post-treatment in the intervention groups was 0.68 standard deviations higher (0.24 to 1.11 higher)
Targeted	behavio	our that challe	nges (proble	ms in man	agement) -	 post-treatment 					
43 (1 study)	serio us ³	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	\bigcirc \bigcirc \bigcirc VERY LOW ^{2,3} due to risk of bias, imprecision	5/24 (20.8%)	7/19 (36.8%)	RR 1.77 (0.67 to 4.7)	208 per 1000	160 more per 1000 (from 69 fewer to 771 more)
Adaptive	functio	ning (social) –	post-treatm	ent (Better	indicated b	by higher values	5)				
85 (1 study)	serio us ¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	45	40	-		The mean adaptive functioning (social) – post-treatment in the intervention groups was 0.47 standard deviations lower (0.9 to 0.04 lower)
Adverse e	events (weight gain; k	(g) – post- tre	eatment (B	etter indica	ted by lower va	lues)				
39 (1 study)	serio us ¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	\bigcirc \bigcirc \bigcirc VERY LOW ^{1,2} due to risk of bias, imprecision	19	20	-		The mean adverse events (weight gain; kg) – post- treatment in the intervention groups was 0.55 standard

											deviations lower (1.19 lower to 0.09 higher)
Adverse	events (drowsiness, r	non-occurrer	nce) – post·	treatment						
42 (1 study)	serio us¹	no serious inconsisten cy	no serious indirectne ss	very serious ²	undetect ed	\bigcirc \bigcirc \bigcirc VERY LOW ^{1,2} due to risk of bias, imprecision	19/20 (95%)	21/22 (95.5%)	RR 1 (0.88 to 1.15)	950 per 1000	0 fewer per 1000 (from 114 fewer to 142 more)
Adverse	events (discontinuatio	on due to ad	verse even	ts, non-occ	urrence) – post-	-treatment				
204 (3 studies)	serio us ⁴	serious⁵	no serious indirectne ss	serious ⁶	undetect ed	 ⊕⊖⊖ VERY LOW^{4,5,6} due to risk of bias, inconsistency, imprecision 	98/103 (95.1%)	80/101 (79.2%)	RR 0.86 (0.71 to 1.04)	951 per 1000	133 fewer per 1000 (from 276 fewer to 38 more)
Adverse	events (discontinuatio	on due to oth	ner reasons	s, non-occu	rrence) – post-t	reatment				
91 (2 studies)	serio us ⁴	very serious ⁷	no serious indirectne ss	serious ⁶	undetect ed	 ⊕⊖⊖ ∨ERY LOW^{4,6,7} due to risk of bias, inconsistency, imprecision 	38/46 (82.6%)	29/45 (64.4%)	RR 0.73 (0.33 to 1.64)	826 per 1000	223 fewer per 1000 (from 553 fewer to 529 more)
² Optimal ³ Crucial li ⁴ Most info $5 l^2 > 40\%$	informat imitation ormation	ion size not me	et; small, sing e criteria suff s at moderate	le study icient to sub	stantially lo	eria sufficient to l wer ones confide				e of effect	

 7 l² > 75%

A.9.19 Melatonin versus placebo in children and young people

Table O.47: Melatonin versus placebo in children and young people

Quality as	ssessmen	it					Summ	ary of fi	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
		r that challeng lower values)		oblem slee	ep behavio	ur) – post-treatme	ent (mea	sured wi	th: Child	ren's Slo	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	_		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
	behaviou by lower		es (global pr	oblem slee	ep behavio	ur) – post-treatme	ent (mea	sured wi	th: Comp	oosite S	eep Disturbance Index; Better
125 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊕⊖⊖ LOW³ due to imprecision 	65	60	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 0.26 standard deviations lower (0.62 lower to 0.09 higher)
Targeted	behaviou	r that challeng	es (non-impr	rovement o	of global pr	oblem sleep beha	viour) –	post-tre	atment		
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\begin{array}{c} \bigoplus \ominus \ominus \ominus \\ VERY \ LOW^{1,2,3} \\ due \ to \ risk \ of \end{array}$	32/32 (100 %)	21/34 (61.8 %)	RR 0.62 (0.48	1000 per 1000	380 fewer per 1000 (from 190 fewer to 520 fewer)

Quality as	ssessmen	t					Summ	ary of fir	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
		r that challeng lower values)		oblem slee	p behaviou	ur) – post-treatme	nt (mea	sured wi	th: Child	ren's Slo	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	_		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
						bias, indirectness, imprecision			to 0.81)		
Targeted	behaviou	r that challeng	es (sleep effi	iciency) – p	oost-treatm	ent (measured wi	th: Acti	graph; B	etter indi	cated by	y higher values)
124 (2 studies)	no serious risk of bias	very serious ⁴	no serious indirectnes s	serious ⁵	undetect ed	 ⊕⊖⊖ VERY LOW^{4,5} due to inconsistency, imprecision 	60	64	-		The mean targeted behaviour that challenges (sleep efficiency) – post-treatment in the intervention groups was 1.46 standard deviations higher (0.51 lower to 3.42 higher)
Targeted	behaviou	r that challeng	es (total slee	ep time) – p	ost-treatm	ent (measured wi	th: Action	graph; Be	etter indi	cated by	/ higher values)
125 (2 studies)	no serious risk of bias	very serious ⁴	no serious indirectnes s	serious ⁵	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{4,5} due to inconsistency, imprecision	61	64	-		The mean targeted behaviour that challenges (total sleep time) – post-treatment in the intervention groups was 1.01 standard deviations higher (0.26 lower to 2.28 higher)

Quality as	ssessmen	it					Summ	ary of fi	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
		r that challeng lower values)		oblem slee	ep behavio	ur) – post-treatme	ent (mea	sured w	ith: Child	ren's Sle	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
Targeted	behaviou	r that challeng	jes (wake afte	er sleep on	set) – post	-treatment (meas	ured wit	h: Actig	raph; Bet	ter indic	ated by lower values)
115 (2 studies)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ⁵	undetect ed	⊕⊕⊕⊖ MODERATE⁵ due to imprecision	57	58	-		The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was 0.76 standard deviations lower (1.14 to 0.38 lower)
Targeted	behaviou	r that challeng	jes (sleep on	set latency) – post-tre	atment (measure	d with: /	Actigrap	h; Better	indicate	d by lower values)
66 (1 study)	serious 1	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	32	34	-		The mean targeted behaviour that challenges (sleep onset latency) – post-treatment in the intervention groups was 1.23 standard deviations lower (1.75 to 0.7 lower)
Targeted	behaviou	r that challeng	ges (total slee	ep time) – p	ost-treatm	ent (measured wi	th: Slee	p diary;	Better inc	licated k	by higher values)
169 (3	no serious	serious ⁶	no serious indirectnes	serious ⁵	undetect ed	⊕⊕⊖⊖ LOW ^{5,6}	85	84	-		The mean targeted behaviour that challenges (total sleep

Quality as	ssessmer	it					Summ	ary of fir	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
-		r that challeng lower values)		oblem slee	p behaviou	ur) – post-treatme	ent (mea	sured wi	th: Child	ren's Slo	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	_		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
studies)	risk of bias		S			due to inconsistency, imprecision					time) – post-treatment in the intervention groups was 0.34 standard deviations higher (0.37 lower to 1.05 higher)
Targeted	behaviou	r that challeng	es (number d	of wakes p	er night) –	post-treatment (m	neasured	d with: S	leep diar	y; Bette	r indicated by lower values)
164 (3 studies)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	serious ⁵	undetect ed	⊕⊕⊕⊖ MODERATE⁵ due to imprecision	81	83	-		The mean targeted behaviour that challenges (number of wakes per night) – post- treatment in the intervention groups was 0.06 standard deviations lower (0.49 lower to 0.37 higher)
Targeted	behaviou	r that challeng	es (wake afte	er sleep on	set) – post	-treatment (meas	ured wit	h: Sleep	diary; Be	etter ind	icated by lower values)
172 (3 studies)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	serious⁵	undetect ed	⊕⊕⊕⊖ MODERATE⁵ due to imprecision	85	87	-		The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was

Quality as	ssessmen	t					Summ	ary of fi	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
-		r that challeng lower values)		oblem slee	ep behaviou	ur) – post-treatme	ent (mea	sured wi	th: Child	ren's Sle	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\oplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	_		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
											0.64 standard deviations lower (1.03 to 0.25 lower)
Targeted	behaviou	r that challeng	es (duration	of wakes)	– post-trea	tment (measured	with: SI	eep diar	y; Better	indicate	d by lower values)
163 (3 studies)	no serious risk of bias	serious ⁶	no serious indirectnes s	serious ⁵	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{5,6} due to inconsistency, imprecision	81	82	-		The mean targeted behaviour that challenges (duration of wakes) – post-treatment in the intervention groups was 0.23 standard deviations higher (0.36 lower to 0.82 higher)
Adverse e	events (sc	olomnence/sed	lation, non-o	ccurrence)	– post-trea	atment					
146 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	⊕⊕⊖⊖ LOW ³ due to imprecision	66/76 (86.8 %)	61/70 (87.1 %)	RR 1 (0.89 to 1.14)	868 per 1000	0 fewer per 1000 (from 96 fewer to 122 more)
Adverse e	events (di	scontinuation	due to adver	se events,	non-occur	rence) – post-trea	tment				
146 (1 study)	no serious	no serious inconsistenc	no serious indirectnes	very serious ³	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ³	74/76 (97.4	69/70 (98.6	RR 1.01	974 per	10 more per 1000 (from 29 fewer to 58 more)

Quality as	ssessmer	nt					Summ	ary of fi	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatoni (95% Cl)
		r that challeng lower values)		oblem slee	ep behavior	ur) – post-treatme	ent (mea	sured w	ith: Child	ren's Sle	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	-		The mean targeted behaviou that challenges (global proble sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lowe (2.39 to 1.23 lower)
	risk of bias	У	S			due to imprecision	%)	%)	(0.97 to 1.06)	1000	
Adverse	events (di	scontinuation	due to other	reasons, r	on-occurre	ence) – post-treat	ment				
284 (3 studies)	no serious risk of bias	serious ⁶	no serious indirectnes s	serious ⁵	undetect ed	⊕⊕⊖⊖ LOW ^{5,6} due to inconsistency, imprecision	127/1 44 (88.2 %)	130/1 40 (92.9 %)	RR 1.06 (0.94 to 1.2)	882 per 1000	53 more per 1000 (from 53 fewer to 176 more)
Adverse	events (se	eizure, non-oco	currence) – p	ost-treatm	ent						
146 (1 study)	no serious risk of bias	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊕⊖⊖ LOW³ due to imprecision 	75/76 (98.7 %)	70/70 (100 %)	RR 1.01 (0.98 to 1.05)	987 per 1000	10 more per 1000 (from 20 fewer to 49 more)
	bias imitation fo		or some limita	itions for m	ultiple criteri		,	,	to 1.05)		feffect

Quality as	ssessmen	t					Summ	ary of fi	ndings		
Participa							Study rates (Relativ	Anticip	ated absolute effects
nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	With place bo	With melat onin	e effect (95% CI)	Risk with place bo	Risk difference with melatonin (95% CI)
-		r that challeng lower values)		oblem slee	ep behaviou	ur) – post-treatme	ent (mea	sured wi	th: Child	ren's Sle	eep Habits Questionnaire;
66 (1 study)	serious	no serious inconsistenc y	serious ²	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post- treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
4 l ² > 75%	informatio	n size not met; n size not met	small, single s	study							

A.9.20 Melatonin versus cognitive behavioural therapy in children and young people

 Table O.48: Melatonin versus cognitive behavioural therapy in children and young people

Quality as	ssessme	nt					Sumn	nary of fi	ndings		
Participa nts	Risk of	Inconsistenc y	Indirectn ess	Imprecis ion	Publicati on bias	Overall quality of evidence	Study rates	event (%)	Relativ e effect	Antici	pated absolute effects
(studies) Follow up	bias						With CBT	With melato nin	(95% CI)	Risk with CBT	Risk difference with melatonin (95% CI)
Targeted indicated			ges (global	problem s	leep behavi	iour) – post-treatm	nent (me	easured	with: Chil	dren's	Sleep Habits Questionnaire; Better
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	33	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 0.94 standard deviations lower (1.45 to 0.44 lower)
Targeted	behavio	ur that challen	ges (non-in	nprovemen	t of global	sleep problem beh	naviour)) – post-t	reatment		
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	30/3 3 (90. 9%)	21/34 (61.8 %)	RR 0.68 (0.51 to 0.9)	909 per 100 0	291 fewer per 1000 (from 91 fewer to 445 fewer)
Targeted	behavio	ur that challen	ges (sleep o	onset laten	cy) – post-t	reatment (measur	ed with	: Actigra	ph; Bette	r indica	ated by lower values)
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	33	34	-		The mean targeted behaviour that challenges (sleep onset latency) – post-treatment in the intervention groups was 0.54 standard deviations lower (1.03 to 0.05 lower)

Targeted	behavio	ur that challen	ges (wake a	after sleep	onset) – po	st-treatment (mea	sured w	vith: Acti	graph; Be	etter ind	dicated by lower values)
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2,3} due to risk of bias, indirectness, imprecision 	33	34	-		The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was 0.73 standard deviations lower (1.22 to 0.23 lower)
Targeted	behavio	ur that challen	ges (total s	leep time) ·	– post-treat	ment (measured w	vith: Ac	tigraph;	Better inc	licated	by higher values)
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	33	34	-		The mean targeted behaviour that challenges (total sleep time) – post- treatment in the intervention groups was 0.76 standard deviations higher (0.26 to 1.26 higher)
Targeted	behavio	ur that challen	ges (sleep o	efficiency)	- post-treat	ment (measured v	vith: Ac	tigraph;	Better in	dicated	by higher values)
67 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	33	34	-		The mean targeted behaviour that challenges (sleep efficiency) – post- treatment in the intervention groups was 0.89 standard deviations higher (0.39 to 1.4 higher)
Adverse e	events (o	discontinuatior	n due to oth	er reasons	s, non-occu	rrence) – post-trea	tment				
80 (1 study)	seriou s ¹	no serious inconsistenc y	serious ²	very serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	36/4 0 (90 %)	36/40 (90%)	RR 1 (0.86 to 1.16)	900 per 100 0	0 fewer per 1000 (from 126 fewer to 144 more)
		for one criterion		itations for	multiple crite	eria sufficient to low	er ones	confider	ice in the e	estimate	e of effect

² Applicability- different populations
 ³ Optimal information size not met; small, single study

A.10 Interventions aimed at improving the health and well-being of carers of people with learning disabilities

A.10.1 Cognitive behavioural interventions for family carers versus any control

 Table 0.49: Cognitive behavioural interventions for family carers versus any control

Quality as	sessme	ent					Summa	ary of finding	S		
Participa nts	Risk of	Inconsisten cy	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	Study e (%)	event rates	Relativ e	Anticip	ated absolute effects
(studies) Follow up	bias						With Any contro I	With cognitive behavioural intervention	effect (95% CI)	Risk with any contr ol	Risk difference with cognitive behavioural intervention (95% CI)
Carer hea	Ith and	well-being (de	oression) – p	ost-treatm	ent (Better	indicated by lowe	r values)			
428 (5 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, imprecision	177	251	-		The mean carer health and well-being (depression) – post-treatment in the intervention groups was 0.35 standard deviations lower (0.54 to 0.15 lower)
Carer hea	Ith and	well-being (de	oression) – fo	ollow-up (B	Better indica	ated by lower valu	ies)				
130 (2 studies) 46 to 104 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, imprecision	66	64	-		The mean carer health and well-being (depression) – follow-up in the intervention groups was 0.41 standard deviations lower (0.79 to 0.04 lower)

Quality as	ssessme	nt					Summa	ary of findin	gs		
Carer hea	Ith and	well-being (clir	nically depres	ssed) – po	st-treatmen	t					
111 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,3} due to risk of bias, imprecision	13/58 (22.4 %)	3/53 (5.7%)	RR 0.25 (0.08 to 0.84)	224 per 1000	168 fewer per 1000 (from 36 fewer to 206 fewer)
Carer hea	Ith and	well-being (an	kiety, trait) –	post-treatr	nent (Bette	r indicated by low	ver value	es)			
68 (2 studies)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	serious ²	undetect ed	$\oplus \oplus \ominus \ominus$ LOW ^{1,2} due to risk of bias, imprecision	31	37	-		The mean carer health and well-being (anxiety, trait) – post-treatment in the intervention groups was 0.5 standard deviations lower (1.03 lower to 0.03 higher)
Carer hea	Ith and	well-being (an	kiety, state) –	- post-treat	ment (Bette	er indicated by lo	wer valu	es)			
36 (1 study)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{3,4} due to risk of bias, imprecision 	18	18	-		The mean carer health and well-being (anxiety, state) – post-treatment in the intervention groups was 0.46 standard deviations lower (1.12 lower to 0.2 higher)
Carer hea	Ith and	well-being (me	ntal ill health	n) – post-tre	eatment (Be	etter indicated by	lower va	alues)			
58 (1 study)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{3,4} due to risk of bias, imprecision 	29	29	-		The mean carer health and well-being (mental ill health) – post-treatment in the intervention groups was 2.19 standard deviations lower (2.85 to 1.53 lower)

Quality as	sessme	nt					Summ	ary of finding	s		
Carer hea	Ith and v	well-being (qua	ality of life) –	post-treat	ment (Bette	er indicated by lov	wer value	es)			
58 (1 study)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{3,4} due to risk of bias, imprecision 	29	29	-		The mean carer health and well-being (quality of life) – post-treatment in the intervention groups was 0.87 standard deviations higher (0.33 to 1.41 higher)
Carer hea	Ith and v	well-being (str	ess) – post-ti	reatment (E	Better indic	ated by lower val	ues)				
384 (3 studies)	serio us ¹	serious⁵	no serious indirectnes s	serious ²	undetect ed	 ⊕⊖⊖⊖ VERY LOW^{1,2,5} due to risk of bias, inconsistency, imprecision 	159	225	-		The mean carer health and well-being (stress) – post- treatment in the intervention groups was 0.45 standard deviations lower (0.78 to 0.12 lower)
Carer hea	Ith and v	well-being (str	ess) – follow	-up (Better	indicated I	by lower values)					
76 (1 study) 104 weeks	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{3,4} due to risk of bias, imprecision	27	49	-		The mean carer health and well-being (stress) – follow-up in the intervention groups was 0.43 standard deviations lower (0.9 lower to 0.05 higher)
Carer hea	Ith and v	well-being (clir	nically stress	ed) – post-	-treatment						
111 (1 study)	serio us ⁴	no serious inconsistenc y	no serious indirectnes s	very serious ³	undetect ed	 ⊕⊖⊖ VERY LOW^{3,4} due to risk of bias, imprecision 	17/58 (29.3 %)	2/53 (3.8%)	RR 0.13 (0.03 to 0.53)	293 per 1000	255 fewer per 1000 (from 138 fewer to 284 fewer)
		is from studies on size not met		risk of bias							

Quality assessment

Summary of findings

 ³ Optimal information size not met; small, single study
 ⁴ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect ⁵ l² > 40%

A.10.2 Psychoeducational interventions for family carers versus any control

Table 0.50: Psychoeducational interventions for family carers versus any control

Quality as	ssessme	ent					Summ	nary of finding	js		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study (%)	event rates	Relativ e	Anticipa	ated absolute effects
(studies) Follow up	bias					evidence	With any contr ol	With psychoedu cation	effect (95% CI)	Risk with any contro I	Risk difference with psychoeducation (95% CI)
Carer hea	alth and	well-being (de	pression) – fo	ollow-up (B	etter indica	ted by lower	values)				
75 (1 study) 4 weeks	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	35	40	-		The mean carer health and well-being (depression) – follow-up in the intervention groups was 0.84 standard deviations lower (1.31 to 0.36 lower)
Carer hea	alth and	well-being (bu	rnout) – follo	w-up (Bette	er indicated	by lower valu	ies)				
90 (1 study) 8 weeks	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\begin{array}{c} \bigoplus \ominus \ominus \ominus \\ VERY \\ LOW^{1,2} \\ due \ to \ risk \\ of \ bias, \end{array}$	45	45	-		The mean carer health and well-being (burnout) – follow- up in the intervention groups was 0.35 standard deviations

Quality ass	Quality assessment							<u>g</u> s		
					imprecision				-	lower (0.77 lower to 0.06 higher)
	nitation for one criterior formation size not met			nultiple criteri	a sufficient to	ower or	es confidence	in the est	imate of eff	iect

A.10.3 Support interventions for family carers versus any control

Table 0.51: Parent advisor scheme versus treatment as usual

Quality as	ssessme	ent					Summary of findings				
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of	Study (%)	event rates	Relativ e	Anticipa	ted absolute effects
(studies) Follow up	bias					evidence	With any contr ol	With support interventio ns	effect (95% CI)	Risk with any control	Risk difference with support interventions (95% CI)
Carer hea	alth and	well-being (stro	ess) – post-tre	eatment (B	etter indica	ted by lower v	values)				
28 (1 study)	seriou s ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	 ⊕⊖⊖ VERY LOW^{1,2} due to risk of bias, imprecision 	12	16	-		The mean carer health and well-being (stress) – post- treatment in the intervention groups was 1.21 standard deviations lower (2.04 to 0.39 lower)

² Optimal information size not met; small, single study

A.10.4 Mindfulness interventions for paid carers versus any control

Table 0.52: Mindfulness inter	rventions for paid care	's versus any control

Quality as	ssessme	ent					Summ	nary of finding	gs		
Participa nts	Risk of	Inconsistenc y	Indirectnes s	Imprecis ion	Publicati on bias	Overall quality of evidence	Study (%)	event rates	Relativ e	Anticipa	ated absolute effects
(studies) Follow up	bias						With any contr ol	With mindfulnes s interventio ns	effect (95% CI)	Risk with any contro I	Risk difference with mindfulness interventions (95% CI)
Carer hea	alth and	well-being (me	ental well-bei	ng) – post-	-treatment (Better indicated b	y highe	r values)			
120 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2} due to risk of bias, imprecision	54	66	-		The mean carer health and well-being (mental well- being) – post-treatment in the intervention groups was 0.17 standard deviations higher (0.19 lower to 0.53 higher)
Carer hea	alth and	well-being (me	ental well-bei	ng) – follov	w-up (Bette	r indicated by higl	ner valu	ies)			
120 (1 study) 6 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigoplus \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	54	66	-		The mean carer health and well-being (mental well- being) – follow-up in the intervention groups was 0.28 standard deviations higher (0.08 lower to 0.64 higher)
Carer hea	alth and	well-being (me	ental ill healtl	n) – post-tr	eatment (B	etter indicated by	lower v	alues)			
154 (2 studies)	serio us ³	serious ⁴	no serious indirectnes s	serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{2,3,4} due to risk of bias,	70	84	-		The mean carer health and well-being (mental ill health) – post-treatment in the intervention groups was

Quality as	ssessm	ent					Summ	nary of findir	ngs	
						inconsistency, imprecision				0.54 standard deviations lower (1.06 to 0.02 lower)
Carer hea	alth and	well-being (me	ental ill healtl	h) – follow-	up (Better	indicated by lowe	r values	;)		
154 (2 studies) 6-13 weeks	serio us ³	serious ⁴	no serious indirectnes s	serious ²	undetect ed	⊕⊖⊖⊖ VERY LOW ^{2,3,4} due to risk of bias, inconsistency, imprecision	70	84	-	The mean carer health and well-being (mental ill health) – follow-up in the intervention groups was 0.24 standard deviations lower (0.72 lower to 0.24 higher)
Carer hea	alth and	well-being (st	ress) – post-t	reatment (Better indic	ated by lower value	ues)			
120 (1 study)	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	54	66	-	The mean carer health and well-being (stress) – post- treatment in the intervention groups was 0.17 standard deviations higher (0.19 lower to 0.53 higher)
Carer hea	alth and	well-being (st	ress) – follow	-up (Better	r indicated	by lower values)				
120 (1 study) 6 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigoplus \ominus \ominus \ominus$ VERY LOW ^{1,2} due to risk of bias, imprecision	54	66	-	The mean carer health and well-being (stress) – follow- up in the intervention groups was 0.05 standard deviations lower (0.41 lower to 0.31 higher)
Carer hea	alth and	well-being (bu	irnout) – posi	t-treatment	(Better inc	licated by lower va	alues)			
34 (1 study)	serio us¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias,	16	18	-	The mean carer health and well-being (burnout) – post- treatment in the intervention groups was

Quality as	ssessm	ent					Summ	ary of findin	gs	
						imprecision				0.18 standard deviations lower (0.86 lower to 0.49 higher)
Carer hea	alth and	well-being (bu	rnout) – follo	w-up (Bett	er indicate	d by lower values)				
34 (1 study) 13 weeks	serio us ¹	no serious inconsistenc y	no serious indirectnes s	very serious ²	undetect ed	$\bigcirc \bigcirc \bigcirc$ VERY LOW ^{1,2} due to risk of bias, imprecision	16	18	-	The mean carer health and well-being (burnout) – follow-up in the intervention groups was 0.08 standard deviations lower (0.76 lower to 0.59 higher)
² Optimal	informat ormatior	for one criterio ion size not me n is from studies	t; small, single	e study	nultiple crite	eria sufficient to lowe	er ones	confidence in	the estimate of e	ffect