Table O.31: Aripiprazole versus placebo in children and young people

Quality assessment							Summary of findings				
Participa nts (studies) Follow up	Risk of bias	Inconsistenc y	Indirectn ess	Imprecis ion	Publicati on bias	Overall quality of evidence	Study event rates (%)		Relativ e	Anticipated absolute effects	
							With place bo	With aripipra zole	effect (95% CI)	Risk with place bo	Risk difference with aripiprazole (95% CI)
Targeted behaviour that challenges (severity) – post-treatment (Better indicated by lower values)											
308 (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	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 challen	iges (sever	ity, non-im	provement) – post-treatment					
308 (2 studies)	serio us¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖ VERY LOW¹,2,3 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 of life – post-treatment (Better indicated by higher values)											
243 (2 studies)	serio us ¹	very serious ⁴	serious ²	serious ³	undetect ed	⊕⊖⊖ VERY LOW¹,2,3,4 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 assessment							Summary of findings				
Adverse	events (elevated prola	ctin, non-o	ccurrence)	– post-trea	tment					
313 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW¹,2,3 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 (E	Better indic	ated by lower values)					
216 (1 study)	serio us ⁵	no serious inconsistenc y	serious ²	very serious ⁶	undetect ed	⊕⊖⊖ 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	inically sig	., non-occ	urrence)						
313 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖ VERY LOW¹,2,3 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 LOW¹,2,3 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 us ⁵	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 assessment								Summary of findings				
Adverse events (discontinuation due to adverse events, non-occurrence) – post-treatment												
316 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖ VERY LOW¹,2,3 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	Adverse events (discontinuation due to other reasons, non-occurrence) – post-treatment											
316 (2 studies)	serio us ¹	no serious inconsistenc y	serious ²	serious ³	undetect ed	⊕⊖⊖⊖ VERY LOW¹,2,3 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)	

¹ Most information is from studies at moderate risk of bias

Applicability – different populations
 Optimal information size not met
 I² > 75%

⁵ Crucial limitation for one criterion or some limitations for multiple criteria sufficient to lower ones confidence in the estimate of effect.

⁶ Optimal information size not met; small, single study