Table O.29: Risperidone versus placebo in children and young people

Quality assessment							Summary of findings				
Participants (studies) Follow up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	Study event rates (%)		Relative effect (95% CI)	Anticipated absolute effects	
							With placebo	With risperidone		Risk with placebo	Risk difference with risperidone (95% CI)
Targeted behaviour that challenges (severity) – post-treatment (measured with: End-point score; Better indicated by lower values)											
257 (4 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	undetected	⨁⨁⨀⨀ 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 behaviour that challenges (severity) – post-treatment (measured with: Change score; Better indicated by lower values)											
66 (1 study)	serious[3]	no serious inconsistency	serious[4]	very serious[5]	undetected	⨁⨀⨀⨀ 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 assessment							Summary of findings				
Targeted behaviour that challenges (severity, non-improvement) – post-treatment											
153 (2 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	undetected	⨁⨁⨀⨀ 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 functioning (social) – post-treatment (measured with: Nisonger Child Behaviour Rating Form – Social Compliance[6]; Better indicated by higher values)											
155 (3 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	undetected	⨁⨁⨀⨀ 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 prolactin, non-occurrence) – post-treatment											
228 (2 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	undetected	⨁⨁⨀⨀ LOW[1,2] due to risk of bias, imprecision	119/120 (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-related adverse event; oligomenorrhea, non-occurrence) – post-treatment											
66 (1 study)	serious[3]	no serious inconsistency	serious[4]	very serious[5]	undetected	⨁⨀⨀⨀ 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) – post-treatment (Better indicated by lower values)											
241 (3 studies)	serious[3]	no serious inconsistency	serious[4]	serious[2]	undetected	⨁⨀⨀⨀ VERY LOW[2,3,4] due to risk of	125	116	-		The mean adverse events (prolactin level; ng/ml) – post-treatment in the

Quality assessment							Summary of findings				
						bias, indirectness, imprecision					intervention groups was 3.22 standard deviations higher (1.68 to 4.75 higher)
Adverse events (weight; kg) – post-treatment (measured with: Change score; Better indicated by lower values)											
282 (3 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	undetected	⨁⨁⊖⊖ 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) – post-treatment (measured with: Endpoint score; Better indicated by lower values)											
53 (1 study)	serious[3]	no serious inconsistency	serious[4]	very serious[5]	undetected	⨁⊖⊖⊖ 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, non-occurrence) – post-treatment											
277 (3 studies)	serious[1]	no serious inconsistency	serious[4]	serious[2]	undetected	⨁⊖⊖⊖ VERY LOW[1,2,4] due to risk of bias, indirectness, imprecision	147/148 (99.3%)	115/129 (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/sedation, non-occurrence) – post-treatment											
550 (6 studies)	serious[1]	serious[7]	serious[4]	no serious imprecision	undetected	⨁⊖⊖⊖ VERY LOW[1,4,7] due to risk of bias,	249/283 (88%)	138/267 (51.7%)	RR 0.58 (0.44 to	880 per 1000	370 fewer per 1000 (from 202 fewer to 493 fewer)

Quality assessment							Summary of findings				
						inconsistency, indirectness			0.77)		
Adverse events (seizure, non-occurrence) – post-treatment											
101 (1 study)	serious[3]	no serious inconsistency	no serious indirectness	very serious[5]	undetected	⨁⊖⊖⊖ 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 (discontinuation due to adverse events, non-occurrence) – post-treatment											
340 (4 studies)	serious[1]	no serious inconsistency	serious[4]	no serious imprecision[2]	undetected	⨁⨁⊖⊖ LOW[1,2,4] due to risk of bias, indirectness	175/178 (98.3 %)	158/162 (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 (discontinuation due other reasons, non-occurrence) – post-treatment											
450 (5 studies)	serious[1]	serious[7]	serious[4]	no serious imprecision	undetected	⨁⊖⊖⊖ VERY LOW[1,4,7] due to risk of bias, inconsistency, indirectness	170/235 (72.3 %)	190/215 (88.4%)	RR 1.19 (1.06 to 1.34)	723 per 1000	137 more per 1000 (from 43 more to 246 more)

1 Most information is from studies at moderate risk of bias
[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] I^2 > 40%