Table O.41: Risperidone versus placebo in adults

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; 12 week; Better indicated by lower values)											
88 (2 studies)	no serious risk of bias	serious[1]	no serious indirectness	serious[2]	undetected	⨁⨁⨀⨀ 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 challenges (severity) – post-treatment (measured with: Change-score; 12 week; Better indicated by lower values)											
74 (1 study)	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	undetected	⨁⨀⨀⨀ 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 challenges (severity) – post-treatment (measured with: Endpoint-score; 26 weeks[5]; Better indicated by lower values)											
37 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[4]	undetected	⨁⨁⨀⨀ 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 assessment							Summary of findings				
											higher (0.48 lower to 0.81 higher)
Quality of life – post-treatment (measured with: 12 weeks; Better indicated by higher values)											
58 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[4]	undetected	⊕⊕⊖⊖ LOW[4] 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 life – post-treatment (measured with: 26 weeks[5]; Better indicated by higher values)											
40 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[4]	undetected	⊕⊕⊖⊖ LOW[4] due to imprecision	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 functioning (social) – post-treatment (Better indicated by lower values)											
30 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[4]	undetected	⊕⊕⊖⊖ 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 events (weight gain, non-occurrence) – post-treatment											
31 (1 study)	no serious risk of bias	no serious inconsistency	serious[6]	very serious[4]	undetected	⊕⊖⊖⊖ 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 (somnolence/sedation, non-occurrence) – post-treatment											
108 (2	no serious	very serious[7]	no serious indirectnes	serious[2]	undetected	⊕⊖⊖⊖ 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 assessment							Summary of findings				
studies)	risk of bias		s			due to inconsistency, imprecision	%)	)	(0.28 to 1.47)	1000	
Adverse events (discontinuation due to adverse events, non-occurrence) – post-treatment											
89 (2 studies)	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[4]	undetected	⨁⨁⨁⊖ 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 (discontinuation due to other reasons, non-occurrence) – post-treatment											
166 (3 studies)	no serious risk of bias	no serious inconsistency	no serious indirectness	serious[4]	undetected	⨁⨁⨁⊖ 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] I^2 > 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] I^2 > 75%