Table O.36: Topiramate (plus risperidone) versus placebo (plus risperidone) 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 valproate		Risk with placebo	Risk difference with valproate (95% CI)
Targeted behaviour that challenges (severity) – post-treatment (Better indicated by lower values)											
57 (2 studies)	serious[1]	serious[2]	no serious indirectness	serious[3]	undetected	⨁⊖⊖⊖ 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 behaviour that challenges (severity, non-improvement) – post-treatment											
27 (1 study)	serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	undetected	⨁⊖⊖⊖ 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 events (weight gain; kg) – post-treatment (measured with: Change score; Better indicated by lower values)											
57 (2 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	undetected	⨁⨁⨀⨀ 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 events (weight gain, non-occurrence) – post-treatment											
30 (1 study)	serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	undetected	⨁⨀⨀⨀ 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 events (somnolence/sedation, non-occurrence) – post-treatment											
57 (2 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	undetected	⨁⨁⨀⨀ 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 events (discontinuation due to adverse events, non-occurrence) – post-treatment											
57 (2 studies)	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	undetected	⨁⨁⨀⨀ 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 events (discontinuation due to other reasons, non-occurrence) – post-treatment											
27 (1 study)	serious[4]	no serious inconsistency	no serious indirectness	very serious[5]	undetected	⨁⨀⨀⨀ 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 information is from studies at moderate risk of bias
[2] I^2 > 40%

[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