

Table O.48: Melatonin versus cognitive behavioural therapy 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 CBT	With melatonin		Risk with CBT	Risk difference with melatonin (95% CI)
Targeted behaviour that challenges (global problem sleep behaviour) – post-treatment (measured with: Children's Sleep Habits Questionnaire; Better indicated by lower values)											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ 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 behaviour that challenges (non-improvement of global sleep problem behaviour) – post-treatment											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	30/33 (90.9%)	21/34 (61.8%)	RR 0.68 (0.51 to 0.9)	909 per 1000	291 fewer per 1000 (from 91 fewer to 445 fewer)
Targeted behaviour that challenges (sleep onset latency) – post-treatment (measured with: Actigraph; Better indicated by lower values)											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ 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 behaviour that challenges (wake after sleep onset) – post-treatment (measured with: Actigraph; Better indicated by lower values)											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊖⊖⊖ 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 behaviour that challenges (total sleep time) – post-treatment (measured with: Actigraph; Better indicated by higher values)											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊖⊖⊖ 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 behaviour that challenges (sleep efficiency) – post-treatment (measured with: Actigraph; Better indicated by higher values)											
67 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊖⊖⊖ 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 events (discontinuation due to other reasons, non-occurrence) – post-treatment											
80 (1 study)	serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊖⊖⊖ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	36/40 (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)
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											