

Table O.47: Melatonin 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 melatonin		Risk with placebo	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)												
66 (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	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
Targeted behaviour that challenges (global problem sleep behaviour) – post-treatment (measured with: Composite Sleep Disturbance Index; Better indicated by lower values)												
125 (1 study)		no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetected	⊕⊕⊕⊕ LOW ³ due to imprecision	65	60	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 0.26 standard deviations lower (0.62 lower to 0.09 higher)
Targeted behaviour that challenges (non-improvement of global problem sleep behaviour) – post-treatment												
66 (1 study)		serious ¹	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ VERY LOW ^{1,2,3} due to risk of	32/32 (100%)	21/34 (61.8%)	RR 0.62 (0.48	1000 per 1000	380 fewer per 1000 (from 190 fewer to 520 fewer)

Challenging behaviour and learning disabilities

Quality assessment							Summary of findings				
Participants (studies)	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 melatonin		Risk with placebo	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)											
66 (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	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
						bias, indirectness, imprecision			to 0.81)		
Targeted behaviour that challenges (sleep efficiency) – post-treatment (measured with: Actigraph; Better indicated by higher values)											
124 (2 studies)	no serious risk of bias	very serious ⁴	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ VERY LOW ^{4,5} due to inconsistency, imprecision	60	64	-		The mean targeted behaviour that challenges (sleep efficiency) – post-treatment in the intervention groups was 1.46 standard deviations higher (0.51 lower to 3.42 higher)
Targeted behaviour that challenges (total sleep time) – post-treatment (measured with: Actigraph; Better indicated by higher values)											
125 (2 studies)	no serious risk of bias	very serious ⁴	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ VERY LOW ^{4,5} due to inconsistency, imprecision	61	64	-		The mean targeted behaviour that challenges (total sleep time) – post-treatment in the intervention groups was 1.01 standard deviations higher (0.26 lower to 2.28 higher)

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 melatonin		Risk with placebo	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)											
66 (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	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
Targeted behaviour that challenges (wake after sleep onset) – post-treatment (measured with: Actigraph; Better indicated by lower values)											
115 (2 studies)	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊖ MODERATE ⁵ due to imprecision	57	58	-		The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was 0.76 standard deviations lower (1.14 to 0.38 lower)
Targeted behaviour that challenges (sleep onset latency) – post-treatment (measured with: Actigraph; Better indicated by lower values)											
66 (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	32	34	-		The mean targeted behaviour that challenges (sleep onset latency) – post-treatment in the intervention groups was 1.23 standard deviations lower (1.75 to 0.7 lower)
Targeted behaviour that challenges (total sleep time) – post-treatment (measured with: Sleep diary; Better indicated by higher values)											
169 (3)	no serious	serious ⁶	no serious indirectness	serious ⁵	undetected	⊕⊕⊖⊖ LOW ^{5,6}	85	84	-		The mean targeted behaviour that challenges (total sleep

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Participants (studies)	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 melatonin		Risk with placebo	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)											
66 (1 study)	serious ¹ risk of bias	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
studies)						due to inconsistency, imprecision					time) – post-treatment in the intervention groups was 0.34 standard deviations higher (0.37 lower to 1.05 higher)
Targeted behaviour that challenges (number of wakes per night) – post-treatment (measured with: Sleep diary; Better indicated by lower values)											
164 (3 studies)	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ MODERATE ⁵ due to imprecision	81	83	-		The mean targeted behaviour that challenges (number of wakes per night) – post-treatment in the intervention groups was 0.06 standard deviations lower (0.49 lower to 0.37 higher)
Targeted behaviour that challenges (wake after sleep onset) – post-treatment (measured with: Sleep diary; Better indicated by lower values)											
172 (3 studies)	no serious risk of bias	no serious inconsistency	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ MODERATE ⁵ due to imprecision	85	87	-		The mean targeted behaviour that challenges (wake after sleep onset) – post-treatment in the intervention groups was

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Participants (studies)	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 melatonin		Risk with placebo	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)											
66 (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	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower) 0.64 standard deviations lower (1.03 to 0.25 lower)
Targeted behaviour that challenges (duration of wakes) – post-treatment (measured with: Sleep diary; Better indicated by lower values)											
163 (3 studies)	no serious risk of bias	serious ⁶	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ LOW ^{5,6} due to inconsistency, imprecision	81	82	-		The mean targeted behaviour that challenges (duration of wakes) – post-treatment in the intervention groups was 0.23 standard deviations higher (0.36 lower to 0.82 higher)
Adverse events (solomnence/sedation, non-occurrence) – post-treatment											
146 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetected	⊕⊕⊕⊕ LOW ³ due to imprecision	66/76 (86.8%)	61/70 (87.1%)	RR 1 (0.89 to 1.14)	868 per 1000	0 fewer per 1000 (from 96 fewer to 122 more)
Adverse events (discontinuation due to adverse events, non-occurrence) – post-treatment											
146 (1 study)	no serious	no serious inconsistency	no serious indirectness	very serious ³	undetected	⊕⊕⊕⊕ LOW ³	74/76 (97.4)	69/70 (98.6)	RR 1.01	974 per	10 more per 1000 (from 29 fewer to 58 more)

Quality assessment							Summary of findings				
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							With placebo	With melatonin		Risk with placebo	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)											
66 (1 study)	serious ¹ risk of bias	no serious inconsistency	serious ²	very serious ³	undetected	⊕⊕⊕⊕ VERY LOW ^{1,2,3} due to risk of bias, indirectness, imprecision	32 (%)	34 (%)	- (0.97 to 1.06)	1000	The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
Adverse events (discontinuation due to other reasons, non-occurrence) – post-treatment											
284 (3 studies)	no serious risk of bias	serious ⁶	no serious indirectness	serious ⁵	undetected	⊕⊕⊕⊕ LOW ^{5,6} due to inconsistency, imprecision	127/144 (88.2%)	130/140 (92.9%)	RR 1.06 (0.94 to 1.2)	882 per 1000	53 more per 1000 (from 53 fewer to 176 more)
Adverse events (seizure, non-occurrence) – post-treatment											
146 (1 study)	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious ³	undetected	⊕⊕⊕⊕ LOW ³ due to imprecision	75/76 (98.7%)	70/70 (100%)	RR 1.01 (0.98 to 1.05)	987 per 1000	10 more per 1000 (from 20 fewer to 49 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											

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							With placebo	With melatonin		Risk with placebo	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)											
66 (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	32	34	-		The mean targeted behaviour that challenges (global problem sleep behaviour) – post-treatment in the intervention groups was 1.81 standard deviations lower (2.39 to 1.23 lower)
³ Optimal information size not met; small, single study ⁴ I ² > 75% ⁵ Optimal information size not met ⁶ I ² > 40%											