

Tabulation included studies ADHD

Sangal et al. 2014

Study aim	To evaluate efficacy and safety of eszopiclone compared with placebo in children and adolescents with insomnia associated with ADHD.					
Method	Design: RCT, double blind, placebo-controlled					
	Country: USA					
	Setting: Multicenter study, 63 sites in US.					
Participants	Sample size: 486. High dose: 162; low dose: 163; placebo: 161					
	Population: ADHD children (6-11) and adolescents (12-17) Age: High dose: 11.3(3.0); low dose: 11.4 (3.0); placebo: 11.6 (3.0) Genders, n(%): High dose: 104(65) men; low dose: 103 (63.2) men; placebo: 101 (63.1) male. Sleep difficulty: Complaints of insomnia (parent/patient report) +Latency to persistent sleep >30 min, or WASO >45 min, determined by baseline Polysomnography + daytime functional impairment due to sleep problems.					
	Follow-up time: 12 w.					
	Dropouts: high dose: 36; low-dose: 41; placebo: 38 Sensitivity analysis, ANCOVA – baseline obs. Carried forward in ITT subjects.					
Intervention	Intervention: high dose (2-3mg); low dose (1-2mg).					
	Control: Placebo					
Outcomes	Outcome measures 2.SOL (latency to persistent sleep) - Polysomnography 5. Night awakenings (WASO) - Polysomnography					
Results	Outcome. Change baseline to 12 w follow-up. Latency to persistent sleep and WASO reported by minutes. Analysis by ANCOVA					
		Mean change high-dose	Mean change low-dose	Mean change placebo	Mean diff high- dose vs placebo	Mean diff low-dose placebo
	2	-18.3 (3.9)	-23.4 (3.9)	-25.7 (3.9)	7.33	2.21
	5	-23.4 (3.4)	-16.8 (3.4)	-17.3 (3.4)	-6.04	0.55
Risk of bias	Low					
Comments	Not clearly described procedures for polysomnography measures – aggregated data from several nights? Measurements performed at laboratory?					

Van der Heijden, 2007

Study aim	To investigate the effect of melatonin treatment on sleep, behavior, cognition, and quality of life in children with ADHD and insomnia.
Method	Design: RCT, double blind, placebo-controlled.
	Country: The Netherlands
	Setting: Outpatient clinics for sleep-wake disorders.
Participants	Sample size: 105 (n=53 melatonin; n=52 placebo).

	Population: ADHD and SOI (sleep-onset insomnia) Age, mean (sd): Melatonin: 9.1 (2.3); Placebo: 9.3 (1.8) Gender; n(%): Melatonin: 66.0% boys; Placebo: 82.7% boys. Sleep problem: SOI – defined by clinical assessments: complaints of sleep-onset problems; sleep onset late in the evening; sleep latency >30 min.																																																														
	Follow-up time: 4 w																																																														
	Dropouts: Analysis on ITT basis. No data on analysis type.																																																														
Intervention	Intervention: Melatonin (3-6 mg, depending on body weight). Duration 3 w																																																														
	Control: Placebo																																																														
Outcomes	Outcome measures 1. TST (total time asleep), by actigraphy 2. SOL (sleep latency), by actigraphy 3. Sleep efficiency, by actigraphy 6. Health Related Quality of life, by TACQOL-P 7a. CBCL																																																														
Results	Test for group differences in changes – pre to post treatment- by general linear model. <table border="1"> <thead> <tr> <th></th><th colspan="3">Melatonin</th><th colspan="3">Placebo</th><th>p-value^a</th></tr> <tr> <th></th><th>Pre Mean (sd)</th><th>Post Mean (sd)</th><th>Change Mean (sd)</th><th>Pre Mean (sd)</th><th>Post Mean (sd)</th><th>Change Mean (sd)</th><th></th></tr> </thead> <tbody> <tr> <td>1 (min)</td><td>518.9 (48.3)</td><td>538.7 (55.0)</td><td>19.8 (61.9)</td><td>533.8 (47.8)</td><td>520.2 (47.5)</td><td>-13.6 (50.6)</td><td>0.01</td></tr> <tr> <td>2 (min)</td><td>53.0 (22.0)</td><td>31.7 (30.7)</td><td>-21.3 (33.0)</td><td>47.3 (23.2)</td><td>50.4 (30.4)</td><td>3.0 (31.7)</td><td>0.001</td></tr> <tr> <td>3 (%)</td><td>80.1 (5.5)</td><td>82.7 (7.5)</td><td>2.6 (8.9)</td><td>82.4 (5.7)</td><td>80.3 (5.9)</td><td>-2.1 (7.1)</td><td>0.011</td></tr> <tr> <td>6</td><td>170.4 (19.9)</td><td>179.1 (21.8)</td><td>8.7 (13.0)</td><td>168.8 (22.5)</td><td>176.9 (22.5)</td><td>8.1 (9.1)</td><td>0.82</td></tr> <tr> <td>7</td><td>63.0 (16.0)</td><td>55.1 (18.4)</td><td>-0.8 (8.8)</td><td>61.5 (21.8)</td><td>45.3 (25.7)</td><td>-16.2 (18.2)</td><td>0.083</td></tr> </tbody> </table> ^a p-value for group differences, change pre-post treatment.								Melatonin			Placebo			p-value ^a		Pre Mean (sd)	Post Mean (sd)	Change Mean (sd)	Pre Mean (sd)	Post Mean (sd)	Change Mean (sd)		1 (min)	518.9 (48.3)	538.7 (55.0)	19.8 (61.9)	533.8 (47.8)	520.2 (47.5)	-13.6 (50.6)	0.01	2 (min)	53.0 (22.0)	31.7 (30.7)	-21.3 (33.0)	47.3 (23.2)	50.4 (30.4)	3.0 (31.7)	0.001	3 (%)	80.1 (5.5)	82.7 (7.5)	2.6 (8.9)	82.4 (5.7)	80.3 (5.9)	-2.1 (7.1)	0.011	6	170.4 (19.9)	179.1 (21.8)	8.7 (13.0)	168.8 (22.5)	176.9 (22.5)	8.1 (9.1)	0.82	7	63.0 (16.0)	55.1 (18.4)	-0.8 (8.8)	61.5 (21.8)	45.3 (25.7)	-16.2 (18.2)	0.083
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Hiscock et al. 2019

Study aim	To determine if a behavior sleep program delivered by pediatricians and psychologists practicing in the community, could improve child sleep (primary outcome) and ADHD symptom severity, psychosocial quality of life, behavior, and daily functioning in children with ADHD.
Method	Design: Cluster randomized trial. Compared by usual clinical care.
	Country: Australia
	Setting: Intervention delivered by pediatricians or psychologists in the community.
Participants	Sample size: n=361: 183 (intervention) + 178 (control)
	Population: ADHD 5-13 years
	Age; mean (sd): Intervention: 9.6 (1.7); Control: 9.4 (1.8).

	Gender; n(%) Intervention: 74.9% boys; control: 75.3% boys Sleep disorder (definition): Moderate to severe sleep problems, reported by care giver + meet diagnostic criteria for at least one sleep disorder.																																																																																
	Follow-up time: 3 months + 6 months																																																																																
	Dropouts (intervention): n=32 did not receive intervention. N=31 received 1 session; n=120 received 2 sessions. Handling missing data by multiple imputation methodology.																																																																																
Intervention	Intervention: Two face-to-face sessions including information about sleep, sleep hygiene strategies, formulation of a behavioral sleep management plan tailored for the individual child.																																																																																
	Control: Care as usual from pediatrician, typically without management of sleep problems.																																																																																
Outcomes	Outcome measures (child). 1.TST (Sleep duration) CSHQ 2.SOL (sleep onset delay) CSHQ 4.Sleep quality CSHQ 5.Night Waking CSHQ 6. Peds QL – dimension, psychosocial health summary score. 7a. ADHD Rating scale IV.																																																																																
Results	Outcome. Difference intervention and control, adjusted. With multiple imputation. <table><tr><th></th><th colspan="3">Intervention</th><th colspan="3">Control</th><th colspan="2">Difference (intervention-control) Mean, (95% Ci)*</th></tr><tr><th></th><th>Pre</th><th>3 m</th><th>6 m</th><th>Pre</th><th>3 m</th><th>6m</th><th>3m</th><th>6m</th></tr><tr><td>1</td><td>6.4 (1.6)</td><td>5.0 (1.7)</td><td>5.2 (1.7)</td><td>6.2 (1.6)</td><td>5.6 (1.6)</td><td>5.7 (1.6)</td><td>-0.46 (-1.00;0.09)</td><td>-0.47 (-0.91;-0.03)</td></tr><tr><td>2</td><td>2.6 (0.6)</td><td>1.9 (0.8)</td><td>2.0 (0.8)</td><td>2.5 (0.7)</td><td>2.2 (0.8)</td><td>2.3 (0.8)</td><td>-0.35 (-0.60;0.09)</td><td>-0.29 (-0.48;-0.10)</td></tr><tr><td>4</td><td>58.3 (8.2)</td><td>50.8 (8.2)</td><td>52.0 (8.1)</td><td>58.5 (8.4)</td><td>55.3 (9.2)</td><td>56.1 (8.7)</td><td>-3.49 (- 6.34;-0.64)</td><td>-3.61 (-6.02;- 1.19)</td></tr><tr><td>5</td><td>5.2 (1.8)</td><td>4.4 (1.5)</td><td>4.7 (1.6)</td><td>5.4 (1.7)</td><td>5.0 (1.7)</td><td>5.0 (1.7)</td><td>-0.44 (-0.89;0.01)</td><td>-0.22 (-0.72;0.27)</td></tr><tr><td>6</td><td>48.3 (14.4)</td><td>-</td><td>57.6 (15.3)</td><td>46.9 (13.6)</td><td>-</td><td>54.3 (13.4)</td><td>-</td><td>2.41 (-2.32;7.14)</td></tr><tr><td>7a^a</td><td>39.5 (8.4)</td><td>31.0 (10.5)</td><td>31.4 (10.5)</td><td>39.0 (8.1)</td><td>32.2 (10.8)</td><td>31.1 (10.2)</td><td>-1.39 (-4.97;2.20)</td><td>0.10 (-3.15;3.35)</td></tr></table> Adjusted difference with multiple imputation ^a Parent report .										Intervention			Control			Difference (intervention-control) Mean, (95% Ci)*			Pre	3 m	6 m	Pre	3 m	6m	3m	6m	1	6.4 (1.6)	5.0 (1.7)	5.2 (1.7)	6.2 (1.6)	5.6 (1.6)	5.7 (1.6)	-0.46 (-1.00;0.09)	-0.47 (-0.91;-0.03)	2	2.6 (0.6)	1.9 (0.8)	2.0 (0.8)	2.5 (0.7)	2.2 (0.8)	2.3 (0.8)	-0.35 (-0.60;0.09)	-0.29 (-0.48;-0.10)	4	58.3 (8.2)	50.8 (8.2)	52.0 (8.1)	58.5 (8.4)	55.3 (9.2)	56.1 (8.7)	-3.49 (- 6.34;-0.64)	-3.61 (-6.02;- 1.19)	5	5.2 (1.8)	4.4 (1.5)	4.7 (1.6)	5.4 (1.7)	5.0 (1.7)	5.0 (1.7)	-0.44 (-0.89;0.01)	-0.22 (-0.72;0.27)	6	48.3 (14.4)	-	57.6 (15.3)	46.9 (13.6)	-	54.3 (13.4)	-	2.41 (-2.32;7.14)	7a ^a	39.5 (8.4)	31.0 (10.5)	31.4 (10.5)	39.0 (8.1)	32.2 (10.8)	31.1 (10.2)	-1.39 (-4.97;2.20)	0.10 (-3.15;3.35)
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Tabellering Hiscock 2015.

Study aim	Examine if behavioral strategies designed to improve children`s sleep problems could also improve the symptoms, behavior, daily functioning and
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	working memory of children with ADHD and the mental health of their parents.																										
Method	Design: RCT																										
	Country: Australia																										
	Setting: 21 general pediatric practices																										
Participants	Sample size: 244 (n=122 Intervention; n=122 control).																										
	Population: ADHD Age: 5-12 years old. Intervention: mean=10.3 (sd=1.8) Control: mean=9.9; sd=2.1 Genders: Intervention: n=103 (84%) boys; Control: n=105 (86%) boys. Sleep disorder: Moderate to severe sleep problems, reported by care giver + meet diagnostic criteria for at least one sleep disorder.																										
	Follow-up time: 3 and 6 months																										
	Dropouts: <i>Intervention:</i> n=8 did not receive intervention (n=3 withdrew; n=4 uncontactable; n=1 too busy). 3-month follow-up: n=36 lost to follow-up; 6-month: n=16 lost to follow-up. <i>Control:</i> 3-month follow-up n=33 lost to follow-up; 6-month follow-up: n=33 lost to follow-up. Analysis on ITT basis. Analysis for imputation by: chained equation multiple imputation model																										
Intervention	Intervention: Sleep hygiene practices and standardized behavioral strategies. Delivered by psychiatrists or pediatricians during 2 fortnightly consultations and a follow-up telephone call.																										
	Control: Usual clinical care.																										
Outcomes	Outcome measures 1. TST (sleep duration), Actigraphy* 3. Sleep efficiency, Actigraphy* 4. Sleep quality/sleep difficulties 5. Night awakeings (WASO), actigraphy* 6. Quality of life: Pediatric quality of life 7a. ADHD rating scale IV * from sub-sample. only 3 month f-up ≥ 20 ind per arm)																										
Results	Results from actigraphy. Only 3 m follow-up reported here due to minimum n=20 ind in each arm restrictions. Unadjusted. Effect size by linear regression. Analysis by linear regression. <table border="1" data-bbox="448 1489 1391 1747"> <tr> <th></th><th colspan="3">Difference in change 3m (intervention (n=25) - control (n=29))</th></tr> <tr> <th></th><th>Mean diff</th><th>95% Ci</th><th>Effect size</th></tr> <tr> <td>1 (min)</td><td>10.9</td><td>-19.0 to 40.8</td><td>0.2</td></tr> <tr> <td>3 (%)</td><td>-1.6</td><td>-5.2 to 1.9</td><td>-0.3</td></tr> <tr> <td>5 (min)</td><td>1.5</td><td>-16.9 to 19.9</td><td>0.05</td></tr> </table> Unadjusted mean and (sd), for subjective data. Effect size by regression analysis, with multiple imputation. <table border="1" data-bbox="448 1998 1391 2031"> <tr> <th></th><th>Intervention</th><th>Control</th><th>Effect size (diff)</th></tr> </table>				Difference in change 3m (intervention (n=25) - control (n=29))				Mean diff	95% Ci	Effect size	1 (min)	10.9	-19.0 to 40.8	0.2	3 (%)	-1.6	-5.2 to 1.9	-0.3	5 (min)	1.5	-16.9 to 19.9	0.05		Intervention	Control	Effect size (diff)
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		Pre	3 m	6 m	Pre	3 m	6 m	Pre-3m	Pre-6m
	4	57.8 (8.8)	50.1 (8.3)	53.2 (7.5)	59.0 (7.8)	55.1 (8.6)	55.9 (8.8)	-0.8	-0.6
	6	49.8 (12.5)	61.7 (15.8)	59.0 (15.0)	48.6 (13.8)	51.1 (13.2)	52.1 (13.7)	0.7	0.4
	7a ^a	35.6 (9.4)	29.7 (10.7)	28.4 (10.8)	37.1 (9.9)	33.2 (9.6)	33.8 (9.5)	-0.3	-0.4
^a parent report. Total score. Mean (sd)									
Risk of bias	Some concerns								
Comments									