

1 Supplementary Data

2 Table S1. Characteristics of Included Studies

Table 1. Characteristics of Included Studies

Authors	Total n	Country	Age	Sex Ratio (% boys)	Outcomes	Treatment arm(s)	Control arm(s)	Mode of delivery
Richman 1985 [18]	44	United Kingdom	1-2 years	60%	5, 6	Trimeprazine (30-60mg)	Placebo	In person
Simonoff & Stores 1987 [19]	18	United Kingdom	1-3 years	44%	5, 6	Trimeprazine (45-90mg)	Placebo	In person
Rickert et al., 1988 [30]	33	USA	6-54 months	55%	6,11	Extinction vs Scheduled awakening	Wait-list control + sleep diary	In person
Adams et al., 1989 [31]	36	USA	18-48 months	44%	8	Graduated extinction vs Structure bedtime routine	Wait-list control	In person
Seymour 1989 [33]	45	New Zealand	9 months-5 years	62%	5,6,14	Extinction vs Extinction with document	Wait-list control	In person
France et al., 1991 [23]	30	New Zealand	7-27 months	?	5, 11	Extinction plus Trimeprazine (30mg)	Extinction plus Placebo	In person
Montanari et al., 1992 [21]	60	Italy	1-36 months	?	5	Niaprazine	Chlordesmethul Diazepam	In person
France et al., 1999 [20]	12	New Zealand	6-27 months	58%	2, 5, 6, 10	Trimeprazine (15-30mg)	Placebo	In person
Reid et al., 1999 [34]	46	USA	16-48 Months	53%	8,14	Extinction vs Graduated extinction	Wait-list control + sleep diary	In person
Hiscock et al., 2002 [25]	156	Australia	6-12 months	57%	10	Graduated extinction or Camping out	Wait-list control + psychoeducation on normal sleep	In person
Moore et al., 2007 [35]	19	USA	3-6 Years	42%	8,11,12,14	Extinction	Wait-list control	In person
Hiscock et al., 2007 [26]	309	Australia	6-12 months	54%	10	Graduated extinction or Camping out	Wait-list control + psychoeducation on normal sleep	In person
Mindell et al., 2009a [37]	206	USA	7-18 months	46%	2,3,4,5,6,7,10	Structure bedtime routine	Wait-list control	Internet
Mindell et al., 2009b [37]	200	USA	18-36 months	49%				
Mindell et al., 2011 [24]	264	USA	6-36 months	50%	2,3,4,5,6,7,8,9,10	Sleep Education vs Structure bedtime routine + Sleep Education	Treatment as usual	Internet
Hall et al., 2015 [28]	235	Canada	6-8 months	48%	4,5,9,10,11	Graduated extinction	Wait-list control + psychoeducation on safety	In person
Gradisar et al., 2016 [27]	43	Australia	6-16 months	34%	2,5,6,7	Graduated extinction vs bedtime fading	Wait-list control + psychoeducation on normal sleep	In person and internet
Mindell et al., 2018 [39]	123	USA	3-18 months	46%	1,2,3,4,5,6,7,8,9,10	Structure bedtime routine	Wait-list control	In person
El Rafihi-Ferreira et al., 2019 [36]	62	Brazil	1-5 years	55%	1,5,6,7	Graduated extinction	Wait-list control + sleep diary	In person and paper
Kahn et al., 2019 [22]	91	Israel	9-18 months	61%	5,6,7	Graduated extinction vs Camping out	Two intervention groups	In person
Stevens et al., 2019 [32]	239	USA	6-36 months	48%	2,4,7,10	Sleep Education	Wait-list control	Internet
Rouzafzoon et al., 2021 [29]	92	Iran	2-4 months	55%	2,4,9,11,14	Structure bedtime routine + Sleep Education	Wait-list control + psychoeducation on safety	In person

Note: " or " means that the participants had the choice between these two methods

Mindell et al., 2009 study was split in two (2009a,2009b) to improve the analysis of the two age groups

Outcomes	
1	TSD : Total sleep duration
2	NSD : Night-time sleep duration
3	Total duration of naps
4	Longest self-regulated sleep
5	Number of night-time awakening
6	Duration of night time wakings - WASO
7	sleep onset latency - SOL
8	Bedtime difficulty
9	Score on a sleep questionnaire
10	Consider sleep a problem
11	Number of night-time awakening with signal / Crying
12	Duration of night crying
13	Number of time out of bed
14	Bedtime

4 **Table S2. List of outcomes for randomized controlled studies evaluating a treatment.**

Outcomes	Number of participants (n studies)	Treatment	p-value
Primary outcomes			
Night-time sleep duration	355 (4)	a, b	$p < 0.001$
Longest self-regulated sleep	605 (5)	a, b, d	$p < 0.001$
Number of Night-time awakening	628 (8)	a, b, c, d, e, g	$p < 0.001$
Duration of night time waking	593 (8)	a, b, c, d, e, g	$p < 0.001$
Sleep onset latency	598 (7)	a, b, d, e, g	$p < 0.001$
How difficult was bedtime	364 (7)	a, b, c, d	$p < 0.001$
Sleep score (child sleep questionnaire)	396 (7)	a, b, c, d	$p < 0.001$
Consider sleep a problem	816 (6)	a, b, d, f	$p < 0.001$
Secondary outcomes			
Number of night-time awakening with signal / Crying	344 (6)	a, b, c, d, e	$p < 0.001$
Duration of crying	9 (1)	c	$p < 0.01$
Number of time out of bed	313 (3)	a, b	$p < 0.001$
Bedtime	98 (4)	a, c, d	$p < 0.001$

note: The number of participants indicated here corresponds only to the clinical groups

Treatments: **a**-Sleep education ; **b**-Structure bedtime routine ; **c**-Complete extinction ; **d**-Graduated extinction ; **e**-Bedtime fading ; **f**-Graduated extinction or Camping out ; **g**-Camping out ; **h**-Antihistamine and extinction ; **i**-Antihistamine ; **j**-Benzodiazepine

i and **j**; show no efficacy on the sleep factors measured at the end of the randomized controlled studies in comparison with the control groups

6 **Table S3. List of outcomes for RCTs assessing complete extinction**

	Number of participants (n studies)	Outcomes
Number of nighttime awakenings	30 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.05$
Duration of nighttime awakenings - WASO	26 (2)	The average duration of nighttime awakenings decreased significantly in the intervention group. $p < 0.05$
Bedtime resistance	14 (1)	Bedtime resistance decreased significantly in the intervention group. $p < 0.001$
Sleep score (child sleep questionnaire)	14 (1)	Sleep disorder score observed decreased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings with signal / crying	20 (2)	The average number of nighttime awakenings with signal decreased significantly in the intervention group. $p < 0.05$
Duration of crying	9 (1)	The average duration of crying decreased significantly in the intervention group. $p < 0.01$
Bedtime	44 (2)	Average bedtime significantly earlier (m=28min) in the intervention group. $p < 0.05$

7 **Table S4: List of outcomes for RCTs assessing graduated extinction**

	Number of participants (studies)	Outcomes
Longest self-regulated sleep	117 (1)	The average duration of continuous signal-free sleep increased significantly in the control intervention group. $p < 0.05$
Number of nighttime awakenings	88 (3)	The average number of nighttime awakenings was significantly reduced in the intervention group. $p < 0.001$
Duration of nighttime awakenings - WASO	57 (2)	The average duration of nighttime awakenings was significantly reduced in the intervention group. $p < 0.001$
SOL: sleep onset latency	88 (3)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.001$
Bedtime resistance	25 (2)	Bedtime resistance decreased significantly in the intervention group. $p < 0.001$
Sleep score (child sleep questionnaire)	192 (4)	Sleep disorder score observed decreased significantly in the intervention group. $p < 0.001$
Sleep is considered a problem	117 (1)	The number of parents who consider their child's sleep to be a problem decreased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings with signal / crying	117 (1)	The average number of nighttime awakenings with signal decreased significantly in the intervention group. $p < 0.001$
Bedtime	13 (1)	Average bedtime significantly earlier ($m = 28\text{min}$) in the intervention group. $p < 0.001$

8 **Table S5: List of outcomes for RCTs assessing structured bedtime routines**

	Number of participants (studies)	Outcomes
NSD : Nighttime sleep duration	218 (2)	The average duration of total nighttime sleep increased significantly in the intervention group. $p < 0.001$
Longest self-regulated sleep	351(3)	The average duration of continuous signal-free sleep increased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings	415 (4)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
Duration of nighttime awakenings - WASO	351 (3)	The average duration of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
SOL: sleep onset latency	351 (3)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.001$
Bedtime resistance	229 (3)	Bedtime resistance decreased significantly in the intervention group. $p < 0.001$
Sleep score (child sleep questionnaire)	84 (1)	Sleep disorder score observed decreased significantly in the intervention group. $p < 0.001$
Sleep is considered a problem	351 (3)	The number of parents who consider their child's sleep to be a problem decreased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings with signal / crying	84 (1)	The average number of nighttime awakenings with signal decreased significantly in the intervention group. $p < 0.001$
Number of times the child left the bed	217 (2)	The number of times the child left the bed decreased significantly in the intervention group. $p < 0.01$

9 **Table S6: List of outcomes for RCTs assessing sleep education**

	Number of participants (studies)	Outcomes
NSD : Nighttime sleep duration	217 (3)	The average duration of total nighttime sleep increased significantly in the intervention group. $p < 0.001$
Longest self-regulated sleep	217 (3)	The average duration of continuous signal-free sleep increased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings	96 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
Duration of nighttime awakenings - WASO	96 (1)	The average duration of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
SOL: sleep onset latency	96 (1)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.001$
Bedtime resistance	96 (1)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.05$
Sleep score (child sleep questionnaire)	137 (2)	Sleep disorder score observed decreased significantly in the intervention group. $p < 0.001$
Consider sleep a problem	96 (1)	The number of parents who consider their child's sleep to be a problem decreased significantly in the intervention group. $p < 0.001$
Number of nighttime awakenings with signal / crying	96 (1)	The average number of nighttime awakenings with signal decreased significantly in the intervention group. $p < 0.001$
Number of times the child left the bed	96 (1)	The number of times the child left the bed decreased significantly in the intervention group. $p < 0.01$
Bedtime	96 (1)	Average bedtime significantly earlier ($m = 28 \text{min}$) in the intervention group. $p < 0.05$

10 **Table S7: List of outcomes for RCTs assessing bedtime fading**

	Number of participants (studies)	Outcomes
Number of nighttime awakenings	15 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.01$
Duration of nighttime awakenings - WASO	15 (1)	The average duration of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
SOL: sleep onset latency	15 (1)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.05$

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12 **Table S8: List of outcomes for the RCT assessing scheduled awakening**

	Number of participants (studies)	Outcomes
Number of nighttime awakening	11 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.05$

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14 **Table S9: List of outcomes for the RCT assessing camping out**

	Number of participants (studies)	Outcomes
Number of nighttime awakenings	48 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
Duration of nighttime awakenings - WASO	48 (1)	The average number of nighttime awakenings decreased significantly in the intervention group. $p < 0.001$
SOL: sleep onset latency	48 (1)	The time needed for the child to fall asleep decreased significantly in the intervention group. $p < 0.001$

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16 **Table S10: List of outcomes for RCTs assessing antihistamines**

	Number of participants (n studies)	Outcomes
NSD: Nighttime sleep duration	15 (1)	The mean duration of total nighttime sleep increased significantly in the treatment group. $p < 0.05$
Number of nighttime awakenings	67 (4)	The average number of nighttime awakenings decreased significantly in the treatment group. $p < 0.05$
Duration of nighttime awakenings - WASO	37 (3)	The average duration of nighttime awakenings decreased significantly in the treatment group. $p < 0.05$
Sleep is considered a problem	15 (1)	The number of parents who consider their child's sleep to be a problem decreased significantly in the treatment group. $p < 0.05$

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19 **Table S11: List of outcomes for the RCT assessing Benzodiazepines**

	Number of participants (n studies)	Outcomes
Number of nighttime awakenings	30 (1)	The average number of nighttime awakenings decreased significantly in the treatment group. $p < 0.05$
Duration of nighttime awakenings - WASO	30 (1)	The average number of nighttime awakenings decreased significantly in the treatment group. $p < 0.05$

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21 **Table S12: List of outcomes for the RCT assessing antihistamines combined with complete extinction**

	Number of participants (n studies)	Outcomes
Number of nighttime awakenings	15 (1)	The average number of nighttime awakenings decreased significantly in the treatment group. $p < 0.05$
Number of nighttime awakenings with signal / crying	15 (1)	The average number of nighttime awakenings with signal decreased significantly in the intervention group. $p < 0.05$

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