Participant Flow

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                              ┌─────────────────────────────┐
                              │   Assessed for eligibility  │
                              │         (n=5355)            │
                              └─────────────────────────────┘
                                          │
                                          │        ┌──────────────────────────────────────────┐
                                          │        │  Excluded (n=4800)                         │
                                          │────────│  ♦ Not meeting inclusion criteria (n=4319) │
                                          │        │  ♦ Declined to participate (n=454)         │
                                          │        │  ♦ Uncontactable  (n=27)                   │
                                          │        └──────────────────────────────────────────┘
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                              ┌─────────────────────────────┐
                              │  Parents Contacted for Consent│
                              │ Moderate/severe sleep problems│
                              │         (n=555)             │
                              └─────────────────────────────┘
                                          │
                                          │        ┌──────────────────────────────────────────┐
                                          │        │  Not Enrolled (n=221)                      │
                                          │────────│  ♦ Not interested (n=55)                   │
                                          │        │  ♦ No response (n=154)                     │
                                          │        │  ♦ Sleep no longer a problem (n=12)        │
                                          │        └──────────────────────────────────────────┘
```

Enrolment

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                              ┌─────────────────────────────┐
                              │         Randomised          │
                              │         (n=334)             │
                              └─────────────────────────────┘
```

Randomisation

Allocated to Intervention (n=166)
♦ **Received allocated intervention (n=155)**
- Number of nurses (n = 24)
- Average number of children per nurse (n=6.46), (range 1-14)

♦ **Did not receive intervention (n=11)**
- Uncontactable (n= 2)
- Withdrew (n=1)
- Sleep problem resolved (n=4)
- Cancelled/unable to reschedule (n=4)

Allocated to Control (n=168)

♦ **Received allocated control (n=168)**
- Withdrew (n=0)

Follow up (6 month)

Completed (n =145)

Lost to follow-up* (n=21)

Included in primary analyses:

Primary Outcome, n = 145 (87%)
(Parent surveys, n = 137 (83%))

Completed (n =155)

Lost to follow-up* (n=13)

Included in primary analyses:

Primary Outcome, n = 155 (92%)
(Parent surveys, n = 146 (87%))

Follow up (12 month)

Completed (n =140)

Lost to follow-up* (n=26)

Included in primary analyses:

Primary Outcome, n = 140 (84%)
(Parent surveys, n = 133 (80%))

Completed (n =157)

Lost to follow-up* (n=11)

Included in primary analyses:
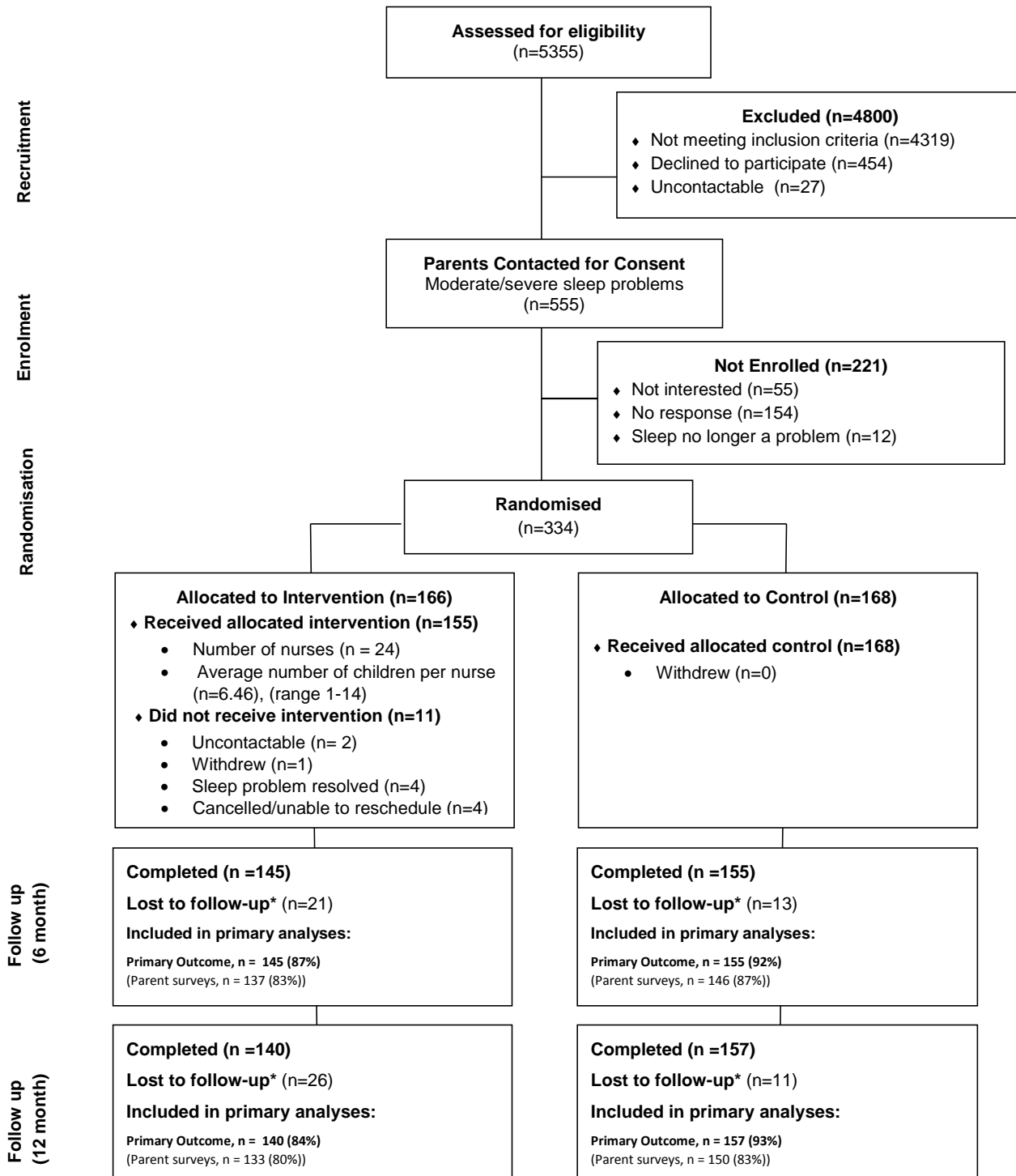
Primary Outcome, n = 157 (93%)
(Parent surveys, n = 150 (83%))

All lost to follow up due to failure to return 6 or 12 month follow up questionnaires.

FIGURE 1:
Intervention CONSORT (Consolidated Standards of Reporting Trials) flow chart

Participant Demographics

Table 1: Sample characteristics at baseline

RCT Child and Family Characteristics at Enrolment		Intervention	Control
Child	Age *Mean* (*SD*)	5.8 (0.37)	5.7 (0.39)
	Male %	48.8	45.2
	1st child %	50.6	54.8
Child sleep	Degree of sleep problem %		
	Moderate problem	70.5	67.3
	Large problem	29.5	32.7
	Bedtime school nights *Mean* (*SD*)	7:48 PM (0:41)	7:49 PM (0:41)
	Bedtime non-school nights *Mean* (*SD*)	8:24 PM (0:51)	8:26 PM (0:55)
	Total sleep duration school nights *Mean* (*SD*), minutes	615.9 (43.2)	611.8 (48.8)
	Total sleep duration non-school nights *Mean* (*SD*), minutes	613.4 (49.0)	612.7 (47.1)
	CSHQ total score *Mean* (*SD*)	53.8 (7.8)	53.7 (8.2)
Child behavior and wellbeing	SDQ prosocial behavior *Mean* (*SD*)	7.9 (2.0)	7.6 (2.0)
	SDQ total difficulties *Mean* (*SD*)	12.1 (6.0)	12.6 (6.1)
	PedsQL psychosocial health *Mean* (*SD*)	69.3 (13.5)	68.4 (13.3)
	PedsQL physical summary *Mean* (*SD*)	72.4 (20.6)	72.5 (18.9)
Primary caregiver	Age *Mean (SD)*	38.8 (6.1)	38.3 (5.1)
	Female %	95.2	92.9
	Biological Parent %	97.0	100
	Marital Status, Married/De Facto %	84.9	85.1
	Highest Education %		
	Did Not Complete Secondary School	15.7	17.3
	Completed Secondary School Only	37.4	33.3
	Completed University Qualification	45.8	49.4
Household	English as Main Language Spoken %	94.6	93.5
	Socio-economic status (SEIFA*) *Mean* (*SD*)	71.6 (20.6)	68.4 (22.8)

Primary and Secondary Outcomes

Table 3: Primary outcomes at 6 and 12 month post-randomization

Outcome	6 months post-randomization					12 months post-randomization				
	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	Effect Size (95% CI)	*p*	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	Effect Size (95% CI)	*p*
Primary Outcome										
PedsQL psychosocial health										

*Data presented (left-right): percentages of children in usual care and intervention groups with moderate/large sleep problem, Odds Ratio (usual care group as reference category) with 95% confidence interval, *p*-value. **Data presented (left-right): medians and interquartile ranges for usual care and intervention groups, Generalised Odds Ratios (usual care group as reference category) with 95% confidence intervals, *p*-values. The generalised Odds Ratio estimates how much more likely the outcome is to improve, compared to worsen, if the participant were to receive the intervention rather than the usual care.

Table 2: Secondary outcomes at 6 and 12 month post-randomization

Outcome	6 months post-randomization				12 months post-randomization			
	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	p	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	p
Parent-report secondary outcomes								
Sleep problem, OR (95% CI)*								
Moderate/severe, %								
CSHQ								
Total score								
Bedtime resistance								
Sleep onset delay								
Sleep duration								
Sleep anxiety								
Night wakings								
Parasomnias								
Sleep disordered breathing								
Daytime sleepiness								
Sleep duration (minutes)								
School nights								
Non-school nights								
Sleep latency (minutes)								
School nights								
Non-school nights								
Quality of life								
PedsQL Physical health								
SDQ behavior								
Total difficulties								
Directly-assessed secondary outcomes								
WIAT-II abbreviated								
Composite score (age norms)								
AWMA								
Digit recall								
Dot matrix								

Outcome	6 months post-randomization				12 months post-randomization			
	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	*p*	Int Mean (SD)	Usual Care Mean (SD)	Mean (I - C) Diff (95% CI)	*p*
Backwards digit recall								
Mister X								
Child self-report secondary outcomes								
Quality of life								
PedsQL Psychosocial health								
PedsQL Physical health								
CHU-9D total score								
Teacher-report secondary outcomes								
SDQ behavior, Gen OR (95% CI)**								
Total difficulties, Median (IQR)								
Academic Rating Scale, Gen OR (95% CI)**								
Language/Literacy, Med (IQR)								
Math Understanding, Med (IQR)								
Student-teacher relationship scale Gen OR (95% CI)**								
Total, Median (IQR)								
Secondary parent outcomes								
Quality of life – EQ-5D								
Index								
Visual Analogue Scale								
DASS- 21 Gen OR (95% CI)**								
Depression, Median (IQR)								
Anxiety, Median (IQR)								
Stress, Median (IQR)								

*Data presented (left-right): percentages of children in usual care and intervention groups with moderate/large sleep problem, Odds Ratio (usual care group as reference category) with 95% confidence interval, *p*-value. **Data presented (left-right): medians and interquartile ranges for usual care and intervention groups, Generalised Odds Ratios (usual care group as reference category) with 95% confidence intervals, *p*-values. The generalised Odds Ratio estimates how much more likely the outcome is to improve, compared to worsen, if the participant were to receive the intervention rather than the usual care.

Adverse Events

No adverse events were experienced during this trial