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Randomized Controlled Trial to Enhance Children’s Sleep, Eating, and Weight

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Abstract

Background: The present study assessed the efficacy of a behavioral intervention to enhance children’s sleep and reduce caloric intake and body mass index (BMI) change.

Methods: Seventy-eight children 8–11 years old who slept 9.5 hours/night or less were randomized to the sleep intervention or to no treatment control. Primary outcome was two-month change in the actigraph-estimated sleep period; changes in reported caloric intake, percent calories from fat, and BMI/BMI z-score (BMIz) were assessed.

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Category of Study: Clinical

Consent Statement: Participating parents provided written consent and participating children provided written assent.

Results: Children randomized to intervention enhanced their sleep period by 40 ± 7 minutes/night relative to control ($p < .001$), and were more likely to increase their sleep period by 30 minutes/night or more (52% versus 15%, $p = .003$). No differences were observed for reported dietary intake or BMI/BMIz. However, in post hoc analyses collapsing across groups, those who increased sleep by 30 minutes/night or more had lower BMI (-0.31kg/m^2 , $p = .01$) and BMIz (-0.07 , $p = .03$) and reported fewer percent calories from fat at two months (-2.2% , $p = .04$).

Conclusions: Brief behavioral intervention can enhance children's sleep, but did not result in changes in caloric intake or weight status. Enhancing sleep by 30 minutes/night or more may be beneficial for weight regulation.

Introduction

Attaining sufficient sleep is important for optimal health and wellbeing.¹ Sufficient sleep in childhood is associated with a number of benefits across domains of functioning,²⁻⁷ and may be particularly relevant for decreasing obesity risk.⁸⁻¹¹ Evidence largely supports eating pathways as a means through which changes in sleep affect changes in weight status.¹² Meta-analysis of randomized experimental studies with adults demonstrates that, relative to control, partial sleep restriction leads to increased energy intake.¹²

Observational studies suggest that enhancing sleep may be particularly beneficial for weight regulation in childhood; meta-analyses demonstrate more robust associations between short sleep and obesity in children relative to adults.^{9,13,14} However, to our knowledge, only one experimental study has been conducted with school-age children;¹⁵ findings were consistent with adult studies. Children reported reductions in caloric intake and weighed less when rested compared to when sleep was restricted.^{15,16} Although findings are compelling, they are limited by imposed experimental sleep conditions, including the prescribed three-hour difference in time in bed between conditions. Thus, the relative clinical utility of enhancing children's sleep for weight regulation is unknown.

The purpose of the present study was to build upon previous work by determining whether a brief behavioral intervention could enhance children's sleep. It also assessed whether the intervention thus positively impacted caloric intake and weight. Specifically, we hypothesized that over the two-month study, relative to control, children randomized to enhance their sleep would achieve a longer nocturnal sleep period, report decreased caloric intake with lower percent calories from fat, and demonstrate smaller changes in BMI than those randomized to control.

Methods

Participants

Eligible children were healthy 8–11-year-olds with reported average time in bed (TIB; reported time between trying to fall asleep and wake) of approximately 9.5 hours per night (hrs/nt), which was confirmed by actigraphy. This threshold was based on work demonstrating benefits of enhancing sleep beyond 9.5 hrs/nt.¹⁵ Additional criteria included BMI-for-age and sex $> 10^{\text{th}}$ percentile, but no greater than 100% overweight (i.e., twice the median BMI for a child's age and sex), to limit potential impact of undiagnosed

conditions; school start time consistent with area elementary schools; understanding and ability to complete the protocol; and reported primary caregiver age ≥ 18 years. Exclusion included reported sleep disorder, medical or psychiatric condition, or medication use that could impact sleep or weight status.

Study Design and Interventions

Families were enrolled into a two-arm, randomized controlled trial between January 2012 and May 2016 using multiple strategies (e.g., direct mailings, community postings). Enrollment occurred in Providence, RI between January 2012 and November, 2013, and in Philadelphia, PA between March, 2014 and May, 2016. Children were primarily enrolled in the study during the school year, but were also enrolled during summer months if they were participating in a structured activity (e.g., day camp, summer school) that mimicked their school-year schedule. This was done to minimize influence of less structured time on study outcomes.^{17,18} Procedures across sites were consistent. Individual or group orientations were conducted in which families were informed of the study's purpose and procedures (i.e., to enhance children's sleep). Written, informed consent was obtained from parents and assent from children.

Prior to randomization, final eligibility was determined during a one-week baseline assessment in which children were asked to sleep as usual. If reported TIB of ≥ 9.5 hrs/nt was confirmed with actigraphy, the child was randomized to study arm by intervention staff using a variable sized, stratified permuted blocks randomization procedure (by weight status and baseline TIB) implemented by the study statistician. Assessments occurred at baseline, two weeks and two months post randomization, and were conducted by staff who remained blind to intervention assignment. Procedures were approved by the institutional review boards at The Miriam Hospital and Temple University. Data and safety monitoring occurred twice yearly by independent safety monitors. No adverse or serious adverse events were reported or observed. This study was registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01508793) (NCT01508793, www.clinicaltrials.gov).

Interventions

Behavioral Sleep Intervention.—Details regarding intervention development have been previously published.²³ Participants received a four-session behavioral intervention that focused solely on enhancing children's TIB by 60–90 minutes/night. It was delivered to parent and child together during two in-person and two phone sessions. The first two sessions focused on effective behavioral strategies to enhance TIB, including goal setting (e.g., bedtimes and wake times), self-monitoring (including via actigraphy periodically), problem-solving/preplanning, stimulus control (i.e., sleep hygiene recommendations), and positive reinforcement. The two phone sessions reinforced strategies to enhance changes in TIB. Between phone sessions children participated in a “sleep challenge” in which they were mailed an actigraph and sleep diary and “challenged” to continue to enhance TIB. “Sleep challenge” results were reviewed during the second call.

Sleep as Usual Condition.—Participants in this condition were asked to continue with their current sleep. To control for contact, the parent and child participated together in two

in-person and two phone sessions. All sessions were educational and focused on appropriate use of study devices and preparation for assessments.

Primary Outcomes

Sleep.—The Actiwatch 2 (AW2; Phillips Respironics, Bend, OR), is a reliable and valid measure of sleep compared to polysomnography.¹⁹ Children wore the AW2 on their non-dominant wrist, 24-hours/day during each one-week assessment. Devices collected data in one-minute epochs using a medium sensitivity threshold. Sleep versus wake was scored using Actiware software version 5.59.0015. Standard procedures²⁰ were used to establish sleep onset and wake. Primary outcome of interest was the sleep period (i.e., time between estimated sleep onset and wake). Additional measures included total sleep time (TST; i.e., minutes of scored sleep during the sleep period), sleep efficiency (i.e., TST/sleep period), bedtime and wake time, and clinically meaningful change in sleep. Previous research indicated that enhancing sleep by approximately 30 minutes/night is associated with improvements in functioning across domains.^{4,21} Thus, we defined *a priori* a clinically meaningful change in the sleep period of 30 minutes/night at two months by taking the difference between sleep period minutes at two months and baseline and then creating groups based on whether the difference was 30 minutes/night.

Caloric Intake.—Caloric (kcal) intake was assessed on two weekdays and one weekend day at each assessment using the United States Department of Agriculture automated multiple pass method for 24-hour dietary recalls, considered the most valid/accurate approach in determining child energy intake.^{22,23} Instructions and aids for portion estimation were provided to families who completed recalls together with blinded staff by phone. The Nutrition Data System for Research (Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN) was used to compute mean daily kcal and mean percent kcal from fat.

Other Measures

Anthropometric Measures.—Trained staff weighed and measured children for height in duplicate while children were dressed in street clothes without shoes using a calibrated digital scale and wall-mounted stadiometer, respectively. Normative age- and sex reference data from the Centers for Disease Control and Prevention were used to calculate weight status.²⁴

Sample Size and Statistical Analysis

A priori sample size estimates were calculated to detect a medium-large effect ($d = .58$, based on preliminary studies²⁵). Presuming two-sided hypothesis testing with type 1 error of 0.05, 80% power, and 93% retention, enrolling 104 children would provide an adequate sample to test aims. We checked for baseline differences between intervention and control conditions on sleep duration, BMI, BMIz, total kcal, and percent kcal from fat. As would be expected due to randomization, no differences between groups were found on baseline variables. Nevertheless, baseline values for each outcome were included in respective models (i.e., baseline BMI included in the model for BMI).

An intent to treat approach to data analyses was employed. Due to repeated measures at two weeks and two months, we fit conditional linear mixed-effects growth models with a random intercept using the lmer function in the R package lme4³⁷ using maximum likelihood estimation separately for each outcome. Assuming any missingness is at random the models account for missingness on the outcome. Thus, all available data from participants are retained. Each model included a main effect for week, main effect for intervention, and an interaction between week and intervention. The model for sleep period also included a main effect for site due to baseline differences on sleep period. The models for BMI and BMIz used only baseline and 2-month assessments; thus, the model was a linear regression model with the baseline assessment included as a covariate. We used alpha of .05 for all tests. Mixed-effects model degrees of freedom for t-tests used the Satterthwaite approximation. Given that baseline sleep duration is measured prior to the intervention, and therefore, cannot be an outcome of the intervention, we included it on the predictor, rather than outcome, side of the model (cite the two references).^{26,27}

A chi square test was used to determine whether children randomized to intervention were more likely to make a change in their sleep period of 30 minutes. We subsequently collapsed across treatment groups to examine whether there were differences between those who did/did not increase their sleep period by 30 minutes; there were no baseline differences between these groups on key demographics or on outcomes. Nevertheless, baseline values for each outcome were included as predictors in the respective models. We fit linear regression models separately for each outcome at 2 months and included a dummy variable indicating whether 30 minutes increase in sleep duration had been achieved. Sensitivity analyses (data not shown) using cut-points of 25, 35, 40, and 45-minute changes in the sleep period yielded consistent results.

Results

One hundred three (99% of target enrollment) children were enrolled in the trial. Following enrollment, 14 (14%) children were determined ineligible based on TIB (confirmed with actigraphy during the baseline assessment), an additional 10 (10%) families were no longer interested post enrollment, and one participant was removed due to an inability to complete study procedures. Thus, 78 (76%) of the 103 enrolled children were randomized and 76 (97%) of the 78 randomized participants completed the study (Fig 1). Of the 78 randomized participants, 38 (49%) were enrolled in Providence, RI and 40 (51%) were enrolled in Philadelphia, PA. Table 1 shows baseline demographics by treatment allocation and for the overall sample. Children were 9.6 ± 1.0 years old and were predominantly female (62%). Approximately half reported identifying as Black. Mean BMIz was 0.85 ± 1.0 .

Thirty-nine (50%) participants were randomized to receive intervention. Attendance at sessions was high with all participants attending the first two in-person sessions, 37 (95%) receiving the first phone follow-up, and 36 (92%) receiving the second phone follow-up session. Attendance and retention were comparable in the control condition with all participants attending the first two in-person sessions and 36 (92%) receiving the first and second phone follow-up sessions. Thus, dose was consistent across conditions, and dose of intervention was delivered as intended.

Relative to those randomized to control, children randomized to intervention enhanced their mean (SD) sleep period by 40 (7) minutes/night across the 2-month study, $t(125.48) = 5.72$, $p < .001$ (Fig. 2). The effect of intervention was maintained between the two-week and two-month assessments (i.e., there was not a significant intervention by week interaction from two weeks to two months). Post-hoc analyses demonstrated that differences in the sleep period were driven by children randomized to intervention going to bed approximately 37 minutes earlier than control, $t(67.85) = 2.41$, $p = 0.019$. Wake times did not differ.

Children randomized to intervention increased their TST, $t(129.64) = 4.43$, $p < .001$. There was also a significant yet modest decrease in sleep efficiency in children randomized to intervention relative to control, $t(116.49) = -2.68$, $p = .01$ (see Table 2). Although children randomized to intervention reported decreasing caloric intake over the two-month study relative to control (-112 ± 78), it did not reach statistical significance, $t(134.48) = -1.44$, $p = .15$. There were no differences between conditions on change in reported percent kcal from fat or BMI metrics (see Table 2).

Post-hoc analyses demonstrated that children randomized to intervention were more likely to achieve a clinically meaningful change in their sleep period of 30 minutes/night or more than those randomized to control, 17 (52%) versus 5 (15%), respectively, $\chi^2(1) = 8.69$, $p = .003$. When collapsed across groups, children who increased their sleep period by 30 minute ($N = 22$) consumed fewer calories from fat (-2.2%) at two months relative to those who did not, $t(63) = -2.10$, $p = .04$. They also had a lower BMI (-0.31 kg/m^2), $t(64) = -2.61$, $p = .01$, and lower BMIz ($-.07$), $t(64) = -2.24$, $p = .03$, at two months. Differences in BMI at two months were due to an increase from baseline of 0.74 kg/m^2 in children who did not increase their sleep period by 30 minutes/night relative to slight decrease of -0.06 kg/m^2 in children who did. No differences were observed in reported caloric intake and no differences were observed in key demographics at baseline between those who did and did not enhance their sleep period by 30 minutes/night or more (Table 3).

Discussion

Findings underscore that a brief behavioral intervention is effective at enhancing school-age children's sleep. Children randomized to intervention enhanced their sleep period relative to control by 40 minutes/night over two months and were more likely to increase their sleep period by 30 minute/night or more. However, intervention did not show effects on reported caloric intake, percent calories from fat, or BMI/BMIz. In contrast, post hoc analyses focused on participants who enhanced their sleep period by 30 minutes/night or more, showed that these children reported significantly lower percent calories from fat, and demonstrated lower BMI/BMIz at two months than children who did not.

Clinical significance of findings is underscored by the myriad benefits of adequate sleep in childhood. Several studies, for example, have shown the benefits of a good night's sleep for improvements in attention,² verbal creativity and abstract thinking,²⁸ and higher school performance.^{2,3} Additional studies with children and adolescents have demonstrated benefits of sleep for mood,⁴⁻⁷ including improvements in reported emotional lability and restless-impulsive behavior⁴ and emotion regulation^{6,7,29} as well as benefits for health,

including beneficial changes in eating behaviors,¹⁵ weight,¹⁵ and glucose regulation^{30–32} when sleep is enhanced.

Few studies to date have focused on enhancing sleep in short sleeping children who do not have a sleep disorder. This is striking given the above-noted benefits of achieving a good night's sleep together with additional studies demonstrating that many children in this country sleep less than is recommended.³³ One school-based sleep education program for adolescents 12–18 years of age did not find any impact of the intervention on sleep duration or timing.³⁴ Thus the present trial makes a substantive contribution by providing evidence for the relative efficacy of a brief behavioral intervention to promote clinically meaningful changes in school-aged children's sleep. Findings also suggest that families are receptive to such intervention - as is underscored by high attendance at treatment sessions and low attrition.

Changes in weight status and reported caloric intake from fat were only observed in children who enhanced their sleep period by at least 30 minutes/night. They were not observed in children randomized to intervention relative to control despite the fact that significantly more children randomized to intervention attained a clinically meaningful change in sleep. Children who improved their sleep period by at least 30 minutes/night demonstrated lower BMIs at two months by 0.31 kg/m² relative to those who did not (primarily due to increases in BMI in children who did not improve their sleep). The observed effect of sleep on weight status is consistent with what has been found in experimental studies with children¹⁵ and adults^{12,35,36}-albeit these previous studies also observed significant changes in caloric intake, which were not found here. A number of reasons could explain why findings here were less, including reliance on self-report of food intake and smaller prescribed changes in sleep within the context of this behavioral intervention relative to experimental studies. It is possible that the effect of intervention could become more robust over time as sleep debt is reduced and children are able to better experience benefits of increased sleep. Alternatively, it is possible that with a larger sample size a significant treatment effect could have been observed.

Strengths of the study include the diverse sample, high retention, and focus on enhancing children's sleep as a novel approach for weight regulation. Limitations include a small study sample and short study timeframe, which may have limited our ability to detect significant effects of intervention. Specifically, although we essentially attained our enrollment goal, fewer participants than expected were randomized in the trial, primarily due to children not being eligible based on their time in bed as measured during the baseline assessment/eligibility week, which was completed post-enrollment. In addition, findings are limited by the one-week assessment of sleep at each time point and limited focus on BMI metrics rather than on measures of fat mass and/or abdominal obesity. Further, analyses that focused on the impact of an improved sleep period of 30 minutes or more were collapsed across treatment groups, which limits conclusions that can be drawn. Future work should assess the relative efficacy of the behavioral intervention at enhancing children's sleep and thus reducing obesity risk in larger samples followed over longer time periods. Better understanding how changes in sleep timing and/or variability could impact outcomes is also an important area for further inquiry.³⁷

Conclusion

In sum, a brief behavioral intervention was effective at enhancing children's sleep relative to control, but did not result in changes in reported caloric intake or in changes in weight regulation. However, post-hoc analyses that collapsed across groups demonstrated that children who achieved clinically meaningful changes in sleep demonstrated benefits in weight regulation and reported intake from fat. Findings add to the growing evidence of the potentially important role of sleep as a novel approach for prevention and/or treatment of obesity in childhood.

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Impact:

- A brief behavioral intervention improved children's nocturnal sleep relative to no treatment control.
- Given the many benefits of a good night's sleep across domains of functioning, findings have significant implications for children's health and wellbeing.
- There were no differences between groups on eating behaviors or BMI.
- However, across groups, children who increased their sleep period by at least 30 minutes/night, reported reduced intake from fat and lower BMI at two months.
- Thus, a brief intervention can improve sleep and may have potential benefits for weight regulation.

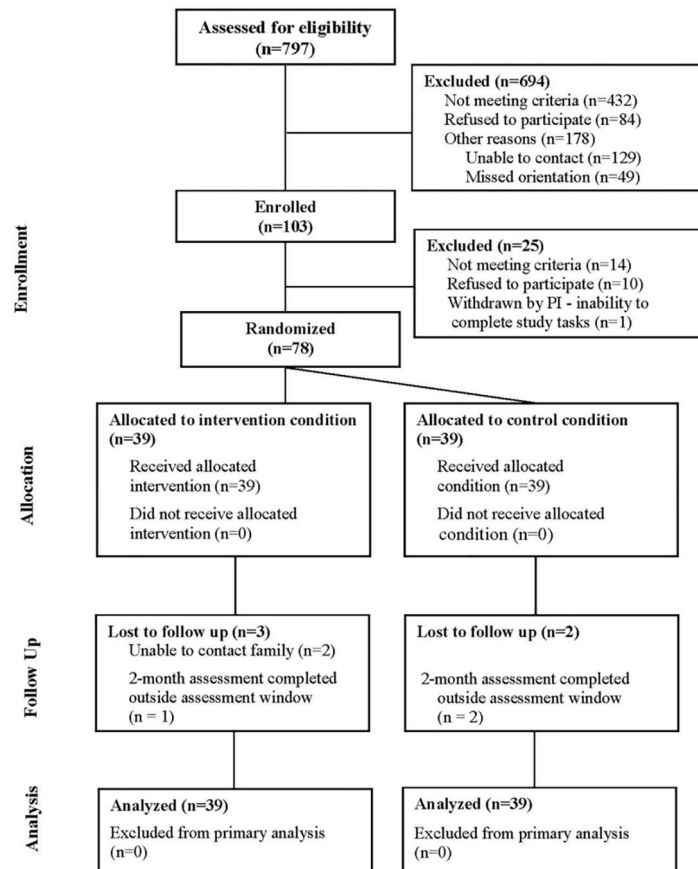


Figure 1.

Consort flow diagram of progress through stages of the randomized trial.

Note. Although five participants were lost to follow up, primary statistical models account for missingness; thus no participants were excluded from primary analysis. Post-hoc analysis that collapsed across groups and focused on change in sleep period from baseline by 30 minutes resulted in 11 participants (i.e., the above-noted five who were lost to follow-up and six participants whose 2-month actigraphy data was deemed unusable due to the watch malfunctioning (4 participants) or nonadherence to the actigraph protocol (two participants)) being dropped from analysis.

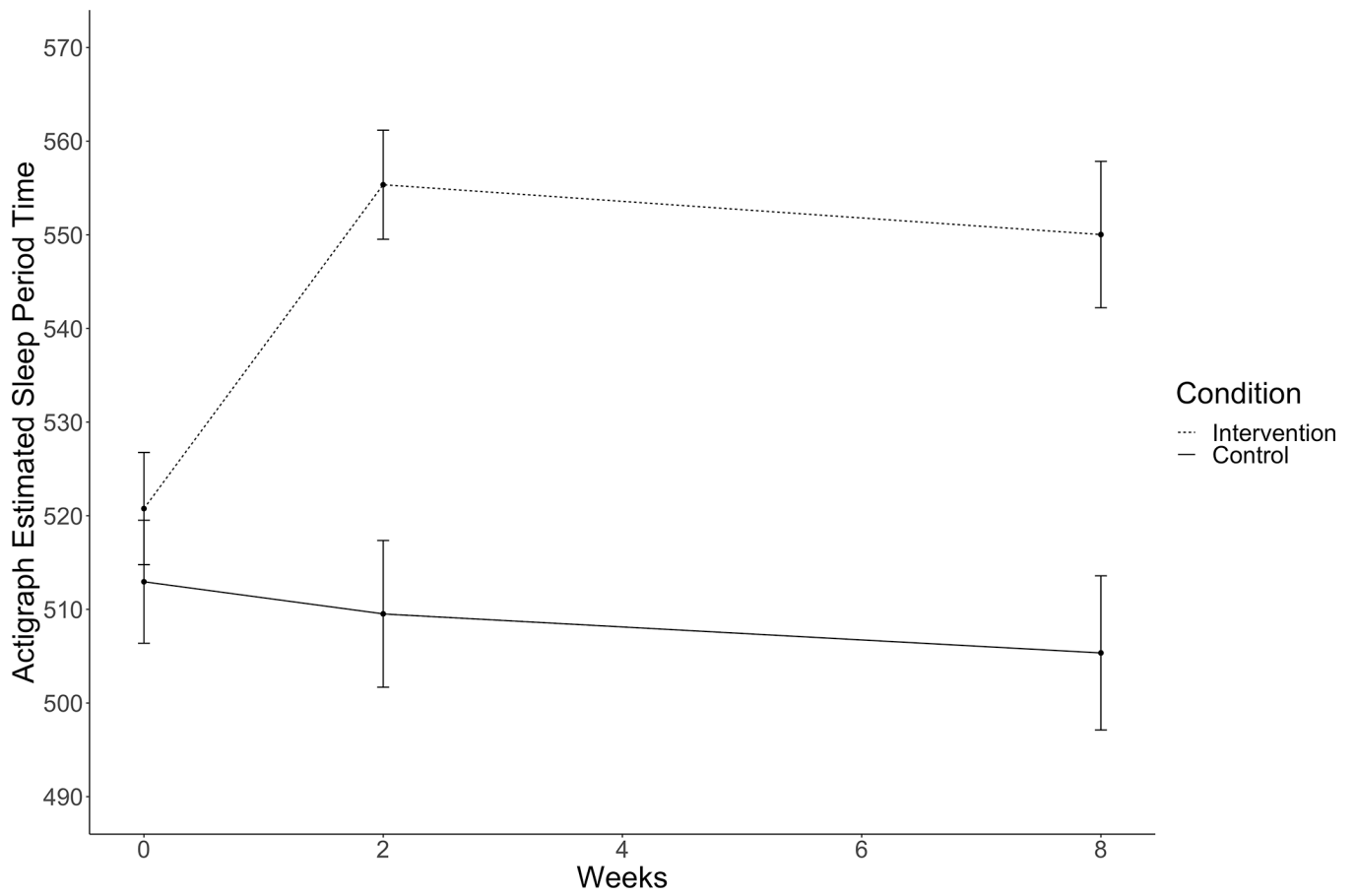


Figure 2. Change in actigraph-estimated sleep period time (minutes/night) by treatment condition (N = 78).

Table 1

Baseline characteristics of the study sample by intervention condition (N=78).

	All (N=78)	Behavioral Sleep Condition (n=39)	Sleep as Usual Condition (n=39)
Location, No. (%)			
Providence, RI	38 (49%)	18 (46%)	20 (51%)
Philadelphia, PA	40 (51%)	21 (54%)	19 (49%)
Child Age (years), mean (SD)	9.7 (1.0)	9.6 (1.0)	9.8 (1.0)
Child Sex, No. (%)			
Female	52 (67%)	24 (62%)	28 (72%)
Child Race, No. (%)			
White	26 (33%)	10 (26%)	16 (41%)
Black	37 (47%)	22 (56%)	15 (39%)
Other	14 (18%)	6 (15%)	8 (21%)
Not Reported	1 (2.5%)	1 (2.5%)	0
Hispanic Ethnicity, No. (%)	12 (15%)	6 (15%)	6 (15%)
BMIz, mean (SD)	0.93 (0.94)	0.84 (1.0)	1.0 (0.88)
Overweight/Obese, No. (%) ^a	36 (46%)	18 (46%)	18 (46%)
Sleep Period (minutes), mean (SD)	517 (39)	521 (37)	513 (41)
Caloric Intake, mean (SD)	1807 (407)	1865 (450)	1749 (354)
Percent Kcal from Fat, mean (SD)	31.1 (4.7)	30.6 (4.1)	31.6 (5.3)

Note:

^aPercent overweight/obese defined as BMI percentile ≥ 85th percentile for age and sex using the CDC normative reference data.²⁴

Table 2.

Child Sleep, Reported Eating Behaviors, and Body Mass Index Scores at Baseline and Two-Month Follow-Up (N = 78).

	Baseline		Two-Month Follow-Up		<i>t</i>	<i>p</i>
	Control	Intervention	Control	Intervention		
Actigraph Estimated Sleep Period (min/night)	513 (41)	521 (37)	504 (47)	551 (45)	5.72	< .001
Actigraph Scored Sleep Minutes (min/night)	456 (38)	464 (36)	450 (43)	485 (46)	4.43	< .001
Sleep Efficiency	89.0 (3.7)	89.3 (3.4)	89.3 (3.5)	88.1 (3.5)	-2.68	< 0.01
Reported Caloric Intake (kcal/day)	1749 (354)	1865 (450)	1802 (369)	1803 (449)	-1.44	0.15
Reported Percent Calories from Fat (kcal/day)	31.6 (5.3)	30.6 (4.1)	32.7 (3.9)	31.0 (5.1)	-1.26	0.21
Body Mass Index (kg/m ²)	20.7 (4.0)	20.3 (4.2)	20.9 (4.1)	20.6 (4.3)	-0.05	0.96
Body Mass Index z-score	1.02 (0.9)	0.84 (1.0)	1.05 (0.88)	0.89 (1.0)	0.78	0.44

Note: All models are linear mixed effects models except for BMI and BMI z-score, which are linear regression models for the two-month assessment, controlling for baseline assessments.

Table 3

Baseline Demographic Characteristics of Children who Did and Did Not Increase their Sleep Period by Thirty Minutes or More (N = 67)^a.

	Increased Sleep ≥ 30 minutes/night (n=22)	Increased Sleep < 30 minutes/night (n=45)
Location, No. (%)		
Providence, RI	11 (50.0)	22 (48.9)
Philadelphia, PA	11 (50.0)	23 (51.1)
Child Age (years), mean (SD)	9.82 (1.01)	9.71 (1.04)
Child Sex, No. (%)		
Female	14 (63.6)	32 (71.1)
Child Race, No. (%)		
White	7 (31.8)	15 (33.3)
Black	11 (50.0)	20 (44.4)
Other	3 (13.6)	10 (22.2)
Not Reported	1 (4.5)	0 (0.0)
Hispanic Ethnicity, No. (%)	4 (18.2)	7 (15.6)
BMIz, mean (SD)	0.77 (0.92)	1.02 (0.94)
Sleep Period (minutes), mean (SD)	517 (27)	513 (43)

Note:

^aThe sample size in these post-hoc analyses is reduced due five participants being lost to follow-up/completing the two-month assessment beyond the assessment window, and six participants having unusable actigraphy data at the two-month assessment (four due to an actigraph malfunction and two due to nonadherence to the actigraphy protocol).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see consort for abstracts)	3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6–8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5–6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5–6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5–6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	8–9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	8–9
Results			

Section/Topic	Item No	Checklist item	Reported on page No
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	9 + Flow diagram
	13b	For each group, losses and exclusions after randomisation, together with reasons	9 + Flow diagram
Recruitment	14a	Dates defining the periods of recruitment and follow-up	5
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Flow diagram
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	9–10; table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	9–10
Harms	19	All important harms or unintended effects in each group (for specific guidance see consort for harms)	6
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	10–13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	10–13
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1, 18

* We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.