Research Square

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Feasibility of Self-Administered Electroencephalography-Based Sleep Assessment in Children and Adults: Data From The SCREENS Pilot Trial

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Abstract

Background Sleep is a crucial part of our lives and insufficient sleep has been linked to several health disorders in both children and adults. However, most studies are based on single night laboratory polysomnography, actigraphy, or sleep diaries. The primary aim of this study was to evaluate the feasibility of a novel self-administered electroencephalography-based (EEG-based) sleep assessment protocol in a sample of children and adults for six nights. The secondary aim was to report sleep parameters derived from the Zmachine.

Methods We analyzed data from 12 families who participated in the SCREENS pilot trial (2018-2019). Children (n=14) and adults (n=19) had to undergo three nights of EEG-based sleep assessment at baseline and follow-up. We assessed compliance to the sleep assessment protocol and summarized perceived feasibility in children and adults. Summary estimates were computed for several sleep parameters.

Results Compliance to the sleep assessment protocol was high with 92.9 % and 89.4% of children and adults meeting the a priori specified compliance goal of at least two out of three nights of complete sleep data at both baseline and follow-up. In general, the protocol was perceived as feasible, with low prevalence of sleep disruption and only minor issues, e.g. difficulties with removing sensors. Results on sleep parameters indicate large within group variation.

Conclusions Our findings support the use of a self-administered EEG-based habitual sleep assessment protocol, including multiple days of measurement, in children and adults.

Trial registration Cilinicaltrials.gov: NCT03788525 [Secondary outcome measures; Retrospectively registered; 27th December, 2018] https://clinicaltrials.gov/ct2/show/NCT03788525 .

1 Background

Sleep is an essential part of our lives and important in terms of health and development across the lifespan. A systematic review and meta-analysis of prospective cohort studies found that short sleep duration was associated with diabetes, cardiovascular disease, coronary heart disease, obesity, and mortality in adults.[1] Furthermore, a systematic review of reviews including primarily observational studies found substantial evidence that sleep duration is associated with obesity and emotional symptoms in children.[2]

Prolonged use of screen media has been linked to sleep disturbances in children and adults in observational studies and some screen time reduction interventions have been found to improve total sleep time.[3, 4] However, almost all observational and experimental studies on this topic are limited by the use of self-reported sleep measures which are susceptible to recall- and social desirability bias.[3, 4] Furthermore, in a screen reduction intervention the participant-reported sleep is likely to be influenced by knowledge of the intervention received by study participants, which increases the risk of bias in a trial.

Although laboratory polysomnography is considered the gold standard in objective sleep assessment[5], some important methodological issues exist when habitual total sleep time is the outcome of interest. One of the main issues is the fact that the polysomnography procedure itself may disrupt an individual's normal sleep because it is performed by mounting multiple sensors to the head, face, and body of a subject who is then

instructed to go to sleep in an unfamiliar laboratory setting.[6] Also, important day-to-day variations in sleep duration may be overlooked because it is often too costly to complete polysomnography for more than one night.

The Zmachine insight + model DT-200 (General Sleep Corporation, Cleveland, OH) is a less expensive and less invasive in-home sleep assessment which may overcome some of the limitations of polysomnography in assessing habitual sleep parameters. The Zmachine utilizes single channel electroencephalography (EEG) data from two sensors placed at the mastoids (A_1 and A_2) to record the electrical activity of the brain. The EEG-signal is processed into sleep stages by the Zmachine algorithm.[7, 8] Though, the Zmachine is a promising tool, only one study have examined the feasibility of this device in adolescents.[9]

Thus, the primary aim of this paper is to evaluate the feasibility of EEG-based sleep assessment (Zmachine) in children and adults under free living conditions in a pilot trial preceding a definitive randomized controlled trial (the SCREENS trial). The secondary aim is to present baseline, follow-up, and change scores of sleep parameters derived from the Zmachine to inform future studies using similar assessment strategies.

2 Methods

The SCREENS pilot trial (www.clinicaltrials.gov – NCT03788525) is a two-arm parallel group cluster randomized trial with two intervention groups and no control group. Data for this trial was collected between October 2018 and March 2019. The overall purpose of the pilot trial was to assess compliance to the included interventions and the included measurement protocol, as well as feasibility of the survey-based recruitment strategy.

The collection of data was reported to the local data protection department SDU RIO (ID: 10.391) in agreement with the rules of the Danish Data Protection Agency.

Participants

Families in the municipality of Middelfart in Denmark were invited to participate if they had at least one child aged 6-10 years residing in the household (n=1686). A digital letter with a survey concerning screen media habits in the family was sent directly to a randomly chosen parent in each household in October 2018. In addition to the survey, a short description of the SCREENS pilot trial was provided on the final page. Here, respondents could note if they were interested in hearing more about the study. Based on the survey responses, families were eligible to participate if the randomly chosen parent's total screen media use was above the median amount (2.7 hrs/day) based on all respondents (n=394), and if all children in the household were older than 3.9 years. The latter was to avoid potential disturbances of sleep measurement due to an infant or toddler's pattern of nocturnal awakening.

Eligibility to the trial was assessed further during a phone call. Families had to meet the following inclusion criteria:

- At least one child and one adult in each family had to participate
- All participants had to be able to heavily restrict total leisure screen media use

- Families had to consider their habitual screen media use a problem and be motivated to reduce it for a two-week-period
- Non-participating family members of the household had to respect the conditions which the participants had to follow

Exclusion of participants was based on the following criteria:

- If adults or children resided only part time in the household
- If participants had been diagnosed with a sleep or stress disorder within the last 12 months
- If adults in the household worked night hours
- If family members were not able to do physical activities as part of daily living
- If a family member was diagnosed with a neuropsychiatric or autism spectrum disorder
- If family members were already participating in other studies

Eligible families were informed about the content of the trial at a meeting in their home. Three additional meetings were planned with families who were willing to participate. The purposes of these meetings were to set up baseline measurements (baseline day 1), perform randomization procedure (baseline day 8), and collect measurement equipment (experiment day 15). A phone call was also planned to remind participants to start follow-up measurements (experiment day 8) (Figure 1).

Sample size

Twelve families with at least one child and one adult were deemed sufficient to investigate compliance to- and feasibility of the intervention and assessment methodology. Also, we considered this sample size large enough for potential problems with the intervention or assessment methods to emerge. An a priori sample size calculation was not considered relevant because hypothesis testing of efficacy was not an aim in the pilot trial.

Interventions

Included families were randomized to one of two screen media restriction interventions; a general restrict or evening restrict group. Those in the general restrict group had to hand over smartphones and tablets and restrict all leisure screen media use for entertainment purposes to a maximum of three hours/week/person for two weeks. Families randomized to the evening restrict group had to remove all leisure screen media use after six PM for two weeks. A more thorough description of the components of the intervention can be found elsewhere (www.clinicaltrial.gov (NCT04098913 under "*Arms and interventions*").

The random sequence generation was performed by Odense Patient Explorative Network Randomise (OPEN R). An online platform provided by OPEN R was used to perform randomization in the home of the participants ensuring allocation concealment until the screen time intervention was assigned. The randomization was made in alternating blocks of two-four families and was stratified by sibling status (only child/not only child) in the household.

Measurement protocol

Families underwent an extensive measurement protocol at baseline and follow-up spanning seven consecutive days (Figure 1). This paper will focus on the EEG-based sleep assessments. Details on the remaining components of the measurement protocol can be found elsewhere.[10]

Sleep assessment

Sleep was objectively measured in the households for three consecutive measurement nights at baseline and follow-up using a single channel EEG-based sleep equipment (Zmachine). Participants were instructed to wear the equipment on the first night (only at baseline) and the last three nights of the measurement protocol. If a family started baseline measurements on a Wednesday, the sleep assessment nights were Wednesday (test night), Sunday, Monday, and Tuesday). Participants were instructed to attach three sensors to the back of the head approximately 30 minutes prior to bedtime which was defined as "*when you are lying in bed and you are ready to close your eyes and go to sleep*". One sensor was placed on the neck below the hair line (ground) and one behind each ear on the differential mastoids (signal).[8] We custom-made an elastic pocket for the Zmachine, which the participants were instructed to attach to an elastic waist belt at bedtime (Figure 2). We developed the pocket such that the device and its cables could be fixated to the belt and thus eliminate the risk of wire entanglement around the neck during sleep. This solution was mainly developed for children in whom the device had not been tested prior. Participants were instructed to connect the cable to the sensors and the Zmachine just before bedtime.

The Zmachine algorithm categorizes the EEG signal on 30-second epoch basis into five different categories 1) Wake, 2) Light sleep (Stage N1 & N2), 3) Deep sleep (Stage N3), 4) Rapid eye movement sleep (REM-sleep) and 5) sensor problem (if the sensor connection fails). Kaplan et al. found that the Zmachine algorithm has sensitivity (95.5 %) and specificity (92.5 %) when compared to polysomnographic technologists in scoring sleep and wake in adults.[7] Wang et al. compared the Z-PLUS algorithm in conjunction with the Z-ALG algorithm to sleep stages scored by polysomnographic technologists and found that it has high sensitivity ranging between 72 % to 91 % in adults.[7, 8]

Participants also reported bedtimes and time of awakening each day allowing crude calculation of self-reported total sleep time.

Total sleep time was defined as the sum of time scored as light, deep, and REM sleep. Sleep onset latency was calculated as the time from application of the Zmachine equipment to the first epoch scored as sleep. Wake after sleep onset was calculated as the amount of time scored as wake between the first and the last epoch scored as sleep.

Assessment of feasibility

Compliance

A priori, participants completing at least 2 out of 3 nights at both baseline and follow-up, were defined as compliant (see NCT04098913 at www.clinicaltrial.gov under "Secondary outcome measures"). In more specific terms; participants were only considered compliant if they provided 2 out of 3 nights with complete sleep data from the Zmachine.

- A night with complete sleep data was defined as a night in which less than 10 % of the epochs were scored as sensor problems.

Episodes with equipment failure (e.g. due to low battery or disconnection of the cable) was identified by manually looking through the sleep data records in cases where there was a difference of more than one hour between self-reported total sleep time and objectively measured total sleep time. Subsequently, a night was excluded if the sleep data record stopped during the night and no data was collected for the rest of the night (a strong indicator of equipment failure).

Perceived feasibility

Adults also completed a questionnaire on behalf of themselves and each child concerning the perceived feasibility of the sleep assessment. The questionnaire was developed by the authors based on experiences with internal testing of the equipment. The questionnaire contained a variety of questions regarding the use of the sleep equipment, e.g. “to which degree were you bothered by the sleep equipment before, during, or following sleep?” (see Table 3 for an overview of the questions).

Statistical methods

Baseline characteristics were computed using medians and inter quartile ranges for continuous variables and proportions for categorical variables. Characteristics are presented separately for children and adults; within the two intervention groups and for both groups combined.

Degree of compliance to the sleep protocol was calculated as proportions. Perceived feasibility was reported by calculating proportions in each response category.

A mean based on all nights with complete sleep data was calculated for everyone at baseline and follow-up for all sleep parameters. The means are based on sleep data from at least two and maximum three nights for each individual at baseline and follow-up, respectively. Group means and standard deviations were calculated for all sleep parameters at baseline and follow-up. Pearson correlation coefficients were calculated for the correlation between baseline and follow-up scores. Mean group changes and standard deviations in sleep parameters were calculated by subtracting group mean at baseline from group mean at follow-up. Not all sleep parameters followed a strict normal distribution; nevertheless, we present means and standard deviations to inform future sample size calculations. Medians and interquartile ranges for all sleep parameters are also given in Additional file 2. We performed supplementary sample size estimations based on the standard deviations of- and the correlation between the baseline and follow-up scores when scores from both groups were pooled (Additional file 3).

All statistical computations were performed in STATA IC 16 software (Statacorp).

3. Results

A total of 12 families consisting of a total of 14 children and 19 adults agreed to participate. The intervention groups were similar at baseline regarding gender distribution, age, educational level, and number of children and adults per family (Table 1).

No participants dropped out of the study. However, one child did not complete the sleep measurements for more than two nights for unknown reasons. The remaining 32 participants (97.0 %) slept with the Zmachine equipment for all 6 nights. Based on data from all 33 participants we acquired a total of 171 nights (86,4%) with complete sleep data (Figure 3). The proportion of participants with complete sleep data for all six measurement nights was higher among adults compared to children (Table 2). Overall, only 9 % of the participants (n=3) had less than four nights of complete sleep data.

Feasibility of the Zmachine

Compliance

A total of 30 participants were compliant. Degree of compliance was similar between children and adults. Overall compliance was 5.6 % higher in the general restrict group compared to the evening restrict group. (Figure 4).

Sensor problems (<10 %) were present during 3 out of 86 nights at baseline and 10 out of 81 nights at follow-up among compliant participants. These nights were distributed among 3 participants (children=2, adults=1) at baseline and 8 participants (children=4, adults=4) at follow-up.

Perceived feasibility

A total of 16 adults (84.2 % of the sample) completed the perceived feasibility questionnaire. The results are presented in Table 3. Approximately one third of the participants were bothered to a medium or high degree before, during or after sleep. Almost one fifth of the participants reported sleeping poorer, but only a few participants reported more awake periods during sleep and having trouble falling asleep. Around one fourth of the participants were bothered by the cables during sleep. A few participants reported being bothered by the equipment when they got up during the night.

Only two participants found it difficult to apply the sensors, but almost one fifth found it challenging to remove the sensors. Also, around one fifth of the participants reported that it was time consuming to apply the Zmachine. Around two fifths of the participants experienced skin irritation where the sensors were applied, and around half of the parents reported that their child were bothered by glue residue. Yet, no parents reported that sleeping with the equipment made their child sad or unhappy.

Sleep parameters

Baseline, follow-up measurements, correlations coefficients, and average two-week change in sleep parameters are presented in Table 4. Sleep parameters were relatively similar between groups at baseline except from total sleep time in children. Standard deviations indicate large within group variation. Change in total sleep time was positive among adults in both intervention groups and children in the general restrict group, while mean change in total sleep time was negative among children in the evening restrict group (for more details see Additional file 1).

We also conducted sample size calculations for total sleep time, sleep onset latency and wake after sleep onset applying the observed baseline and follow-up scores, and the correlation between them (Additional file 3).

4. Discussion

Based on the children and adults from the SCREENS pilot trial, compliance to the EEG-based sleep assessment protocol was very high with 90.9 % of the participants having complete sleep data. Furthermore, perceived feasibility of the Zmachine equipment indicated low prevalence of assessment-related sleep disruption, high participant acceptance, and the use of the equipment was overall deemed feasible. Few participants experienced minor challenges, e.g. removing the sensors. Standard deviations indicated relatively large within group variation in sleep parameters.

Feasibility

This study provides novel results on the feasibility of self-administered use of the Zmachine in a free-living context in children and adults. Compliance was high, which is especially interesting considering the already heavy measurement load that participants were under during the course of this study (i.e. accelerometry, HRV, saliva sampling (only adults), and daily self-report). Also, importantly, the proportion of children with complete sleep data for at least two nights at baseline and follow-up was comparable to that of the adults. We expected more missing data among the children relative to the adults, due to more frequent displacement of sensors.[11] Our custom-made elastic pocket may have prevented cable disconnection from occurring.

The participants reported overall that the protocol was feasible, with only minor issues such as skin irritation, glue residue, and being bothered by the cables during sleep. However, the severity of the irritations remains unclear due to the nature of the questions (yes/no), which gives an unnuanced picture of the issues. However, the field researchers (MGBR and JP) did not receive oral or written complaints of any skin lesions or other serious problems with the sleep sensors, only minor issues such as reddening of the skin. Children did not complain noticeably more than adults, except when asked about being bothered by e.g. removing the sensors and glue residue, which we expected. Based on the results of this study we recommend using the Zmachine in combination with an elastic pocket attached to an elastic waist belt in children (Figure 2).

Lunsford-Avery et al. has also evaluated the feasibility of the Zmachine (without use of a custom-made pocket). The study included 104 adolescents who had to sleep with the Zmachine for seven days. They found that 87 % had at least 3 full nights of sleep EGG recordings. Additionally, they found that 81 % of the participants rated the equipment as comfortable to mildly uncomfortable. Also, around 20 % of the participants reported sleeping poorer due to the sleep assessment.[9] These results are in line with the results of our study where 90.9 % had complete sleep data for at least 4 out of 6 nights, while around one third reported being bothered to a medium or high degree before, during or after sleep, and 17.2 % reported sleeping poorer.

Few studies have evaluated other EEG-based sleep set-ups. A study by Marcus et al. examined the feasibility of single night unattended ambulatory polysomnography, where a sleep technologist applied the equipment to the child in their home. The study included 201 school-aged children and found that unattended ambulatory polysomnography is a feasible and well-tolerated method in school-aged children. Marcus et al. also found that 93.5 % of the participants had a satisfactory EEG-signal.[6] These results are also similar to the results found in children in our study where the proportion of children who had complete data was 92.9 %. A study by Mikkelsen et al. investigated the feasibility of sleeping with dry contact ear-EEG in 20 adults in a sleep laboratory.[12] They found that 80 % of the participants reported the ear-EEG as easy to use, which is slightly lower compared to the

results of our study where 93.8 % did not find it challenging to apply the sensors. In addition, Mikkelsen et al. found that 20 % rated their sleep quality as bad with the ear-EEG, which is comparable to our study.

Based on the similarity between results from Lunsford-Avery et al., Marcus et al., Mikkelsen et al. and our study it is worth emphasizing that the participants in Lunsford-Avery et al. and our study applied the equipment themselves for several consecutive nights following instructions whereas it was applied by research personnel on all measurement nights in the other studies. This indicates that the Zmachine is a feasible method for EEG-based evaluation of habitual sleep parameters.

Sleep parameters

We observed large standard deviations in sleep parameters across intervention groups in children and adults. This may to some extent be due to the small sample or the fact that sleep was measured for only three nights. In some families the protocol included one weeknight and two weekend nights, while in other families it was the opposite depending on what day of the week the assessment protocol was initiated. Also, it is well known that individual sleep parameters may vary widely from day to day[13], which also might explain some of the observed variation in sleep parameters. These considerations should be considered when looking at the estimated sample size examples in Additional file 3. Nevertheless, to our knowledge it is the best available data to qualify a sample size for a future parallel randomized controlled trial investigating the efficacy of a short-term behavioral intervention on habitual sleep parameters derived from the Zmahcine in children and adults.

Limitations

This study has some limitations which must be kept in mind when interpreting the results. First, the sample consists of families who accepted an extensive protocol and intervention, which may have caused that the participants are from households that are particularly resourceful. Secondly, the perceived feasibility questions have not been validated and therefore some issues with the use of the Zmachine may have been overlooked or overestimated. However, participants had an opportunity to write free text answers, which very few participants chose to do. Thirdly, perceived feasibility data was not available for all participants. Fourthly, no studies have evaluated the Z-ALG and Z-PLUS algorithms in children, thus the accuracy is unclear. However, the Zmachine is programmed to develop a sleep signature based on the first recording, because EEG signal varies with e.g. age. Finally, we evaluated the feasibility of the Zmachine protocol in combination with other physical assessment methods that may have influenced perceived feasibility negatively due to the overall participant burden. Thus, we expect that the compliance and perceived feasibility of the Zmachine is even greater as an isolated sleep assessment tool.

Conclusions

Collectively, the findings of this study indicate that the Zmachine is a feasible and tolerated method to assess habitual sleep parameters using a protocol with three consecutive nights in children and adults.

Abbreviations

EEG: electroencephalography

REM: Rapid eye movement

Declarations

Ethical approval and consent to participate

The SCREENS pilot trial was approved by the Ethical Committee of Southern Denmark (S-20170213). Written informed consent was obtained before starting baseline measurements.

Consent for publication

Consent for publication of the image in Figure 2 was given by the child and his parents prior to submission.

Availability of supporting data

The datasets generated and analysed during the current study are not publicly available due to the general data protection regulations but will be shared on reasonable request using a safe platform by the corresponding author.

Competing interests

All authors declare no financial or non-financial competing interests.

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Authors' contributions

Idea and funding of study: AG, Additional development of the study design: All authors, Data collection: MGBR and JP, Data management and analyses: MGBR, JP, Wrote first draft: JP, Approved manuscript: All authors.

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Figure 1 is re-used from figure 3 in Rasmussen, M.G.B., Pedersen, J., Olesen, L.G. *et. al.* Short-term efficacy of reducing screen media use on physical activity, sleep, and physiological stress in families with children aged 4–14: study protocol for the SCREENS randomized controlled trial. *BMC Public Health* 20, 380 (2020). https://doi.org/10.1186/s12889-020-8458-6, under the Creative Commons by Attribution license. A small change was made; a small pink arrow was added after the depiction of the baseline period.

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Tables

Table 1

Baseline characteristics. The table shows baseline characteristics of the sample. Medians with 25th and 75th percentiles are presented for all continuous variables, and proportions are presented for categorical variables.

	Evening restrict (17 participants, 6 families)	General restrict (16 participants, 6 families)	All participants (33 participants, 12 families)
Children			
n	7	7	14
Gender (% female)	28.6	28.6	28.6
Age (years)	9 (6–10)	9 (7–10)	9 (7–10)
Participating children per family (n)	1 (1–1)	1 (1–1)	1 (1–1)
Adults			
n	10	9	19
Gender (% female)	60.0	55.6	57.9
Age (years)	42 (38–45)	45 (41–46)	42 (39–46)
ISCED	40.0	33.3	36.8
0-3 (%)	50.0	44.4	47.4
4–6 (%)	10.0	22.2	15.8
7–8 (%)			
Participating adults per family (n)	2 (1–2)	1.5 (1–2)	1 (1–2)

Table 2

– Proportion of participants with complete sleep data. The table above shows the proportion (%) of participants with complete data (< 10% sensor problems) on zero measurement nights to all six measurement nights. All measurement nights with complete sleep data (n = 171) are included.

	0 nights	1 Night	2 nights	3 nights	4 nights	5 nights	6 nights
All participants (%)	0,0	3,0	3,0	3,0	12,1	21,2	57,6
Adults (%)	0,0	0,0	5,3	5,3	0,0	21,0	68,4
Children (%)	0,0	7,1	0,0	0,0	28,6	21,4	42,9

Table 3

– Perceived feasibility of the Zmachine. The table above shows an overview of answers from the perceived feasibility questionnaire. Answers are presented as proportion in each category. *Two children did not answer the child part of the questionnaire because unfortunately the wrong link was sent to their parents.

	Answer categories	All participants (n = 29)	Adults (n = 16)	Children (n = 13)
To which degree were you bothered by the Zmachine before, during, or after sleep?	Very high	0 (0.0)	0 (0.0)	0 (0.0)
	High	1 (3.5)	0 (0.0)	1 (7.7)
	Medium	9 (31.0)	5 (31.3)	4 (30.8)
	Low	5 (17.2)	1 (6.3)	4 (30.8)
	Very low	9 (31.0)	5 (31.3)	4 (30.8)
	Not at all	5 (17.2)	5 (31.3)	0 (0.0)
	I don't know	0 (0.0)	0 (0.0)	0 (0.0)
Do you think that the Zmachine had an influence on your sleep quality?	Yes, I slept poorer	5 (17.2)	4 (25.0)	1 (7.7)
	No	22 (75.9)	11 (68.8)	11 (84.6)
	I don't know	2 (6.9)	1 (6.3)	1 (7.7)
Did you experience more awake periods during sleep?	Yes	4 (13.8)	2 (12.5)	2 (15.4)
	No	25 (86.2)	14 (87.5)	11 (84.6)
Did you have trouble falling asleep because of the Zmachine?	Yes	3 (10.3)	1 (6.3)	2 (15.4)
	No	26 (89.7)	15 (93.8)	11 (84.6)
Did the cables bother you during sleep?	Yes	8 (27.6)	4 (25.0)	4 (30.8)
	No	21 (72.4)	12 (75.0)	9 (69.2)
Did the equipment bother you when you got up during the night?	Yes	2 (6.9)	2 (12.5)	0 (0.0)
	No	27 (93.1)	14 (87.5)	13 (100.0)

	Answer categories	All participants (n = 29)	Adults (n = 16)	Children (n = 13)
Did you find it challenging to apply the sensors?	Yes	2 (6.9)	1 (6.3)	1 (7.7)
	No	27 (93.8)	15 (93.8)	12 (92.3)
Did you find it challenging to remove the sensors?	Yes	5 (17.2)	0 (0.0)	5 (38.5)
	No	24 (82.8)	16 (100.0)	8 (61.5)
Did you experience skin irritation on the spots where the sensors were applied?	Yes	12 (41.4)	6 (37.5)	6 (46.2)
	No	17 (58.6)	10 (62.5)	7 (53.9)
Did you find it time consuming to apply the Zmachine?	Yes	-	3 (18.8)	-
	No	-	13 (81.3)	-
Did you feel like you were being monitored?	Yes	-	0 (0.0)	-
	No	-	16 (100.0)	-
Did sleeping with the Zmachine make your child sad or unhappy? *	Yes	-	-	0 (0.0)
	No	-	-	11 (100.0)
Did your child oppose sleeping with the Zmachine? *	Yes	-	-	0 (0.0)
	No	-	-	11 (100.0)
Was your child bothered by glue residue? *	Yes	-	-	5 (45.5)
	No	-	-	6 (54.6)
Did your child find it challenging to be the only child in the household who had to sleep with the Zmachine? *	Yes	-	-	0 (0.0)
	No	-	-	11 (100.0)

Table 4

– Sleep parameters. The table above shows means (standard deviations) for participants with complete sleep data at baseline and follow-up. Pearson correlations coefficients are provided for the correlation between baseline and follow-up scores. Light sleep corresponds to non-REM sleep stage N1 and N2. Deep sleep corresponds to non-REM sleep stage N3. For baseline, follow-up, and change scores expressed as medians and ranges see Additional file 2.

	Adults *Evening restrict n = 9* *General restrict n = 9* *Both groups n = 18*				**Children** *Evening restrict n = 7* *General restrict n = 6* *Both groups n = 13*			
	Baseline	**Follow-up**	**Change**	**Correlation**	**Baseline**	**Follow-up**	**Change**	**Correlation**
Total sleep time	370.6 (67.1)	386.9 (51.3)	16.3 (71.6)	0.29	521.2 (36.6)	511.8 (23.9)	-9.47 (44.2)	-0.02
				0.87				0.44
(min/night)	369.4 (59.7)	381.8 (59.4)	12.4 (30.7)	0.60	487.1 (26.2)	492.5 (48.8)	5.37 (44.0)	0.31
Evening restrict	370.0 (61.3)	384.2 (54.0)	14.2 (52.1)		505.5 (35.6)	502.8 (37.1)	-2.6 (42.9)	
General restrict								
Both groups								
Sleep onset latency	13.3 (10.6)	10.6 (9.7)	-2.7 (13.0)	0.18	29.7 (14.9)	22.8 (10.0)	-6.94 (10.6)	0.71
				0.15				0.03
(min/night)	15.3 (7.4)	13.9 (8.0)	-1.3 (10.1)	0.18	25.6 (17.5)	28.1 (19.2)	2.4 (25.7)	0.22
Evening restrict	14.3 (8.8)	12.4 (8.7)	-2.0 (11.2)		27.8 (15.6)	25.2 (14.6)	-2.6 (18.8)	
General restrict								
Both groups								
Wake after sleep onset	60.7 (32.9)	45.6 (21.3)	-15.2 (33.3)	0.30	65.0 (31.9)	71.1 (26.7)	6.13 (30.8)	0.46
				0.43				0.81
(min/night)	43.9 (31.6)	43.1 (32.2)	-0.84 (33.8)	0.37	66.8 (25.6)	71.5 (47.6)	4.69 (30.6)	0.60
Evening restrict	51.8 (32.4)	44.3 (26.8)	-7.6 (33.3)		65.8 (27.9)	71.3 (36.1)	5.5 (29.4)	
General restrict								
Both groups								

	Adults *Evening restrict n = 9* *General restrict n = 9* *Both groups n = 18*				Children *Evening restrict n = 7* *General restrict n = 6* *Both groups n = 13*			
	Baseline	**Follow-up**	**Change**	**Correlation**	**Baseline**	**Follow-up**	**Change**	**Correlation**
Light sleep (%)	42.8 (7.6)	46.5 (10.3)	3.7 (5.9)	0.83	47.3 (9.2)	48.2 (8.3)	1.0 (3.3)	0.93
Evening restrict	38.7 (6.1)	43.9 (10.3)	5.1 (8.8)	0.52	48.7 (2.4)	47.0 (4.9)	-1.7 (6.3)	− 0.46
General restrict	40.7 (6.9)	45.1 (10.0)	4.5 (7.4)	0.68	47.9 (6.8)	47.7 (6.7)	-0.26 (4.9)	0.73
Both groups								
Deep sleep (%)	22.6 (6.3)	20.3 (8.3)	-2.3 (5.9)	0.71	20.7 (1.9)	20.4 (2.8)	-0.3 (3.3)	-0.01
Evening restrict	26.2 (5.3)	21.5 (8.9)	-4.7 (4.7)	0.91	19.5 (2.1)	19.6 (2.2)	0.1 (1.9)	0.60
General restrict	24.5 (5.9)	20.9 (8.4)	-3.5 (5.3)	0.78	20.1 (2.0)	20.0 (2.4)	-0.1 (2.7)	0.28
Both groups								
REM sleep (%)	20.3 (6.7)	22.2 (6.9)	1.9 (2.7)	0.92	20.6 (5.3)	19.1 (7.5)	-1.5 (3.6)	0.89
Evening restrict	24.2 (9.8)	24.4 (7.2)	0.2 (3.7)	0.95	19.9 (3.5)	19.8 (6.3)	-0.2 (5.0)	0.60
General restrict	22.4 (8.5)	23.3 (6.9)	1.0 (3.3)	0.93	20.3 (4.4)	19.4 (6.7)	-0.9 (4.2)	0.79
Both groups								

Figures

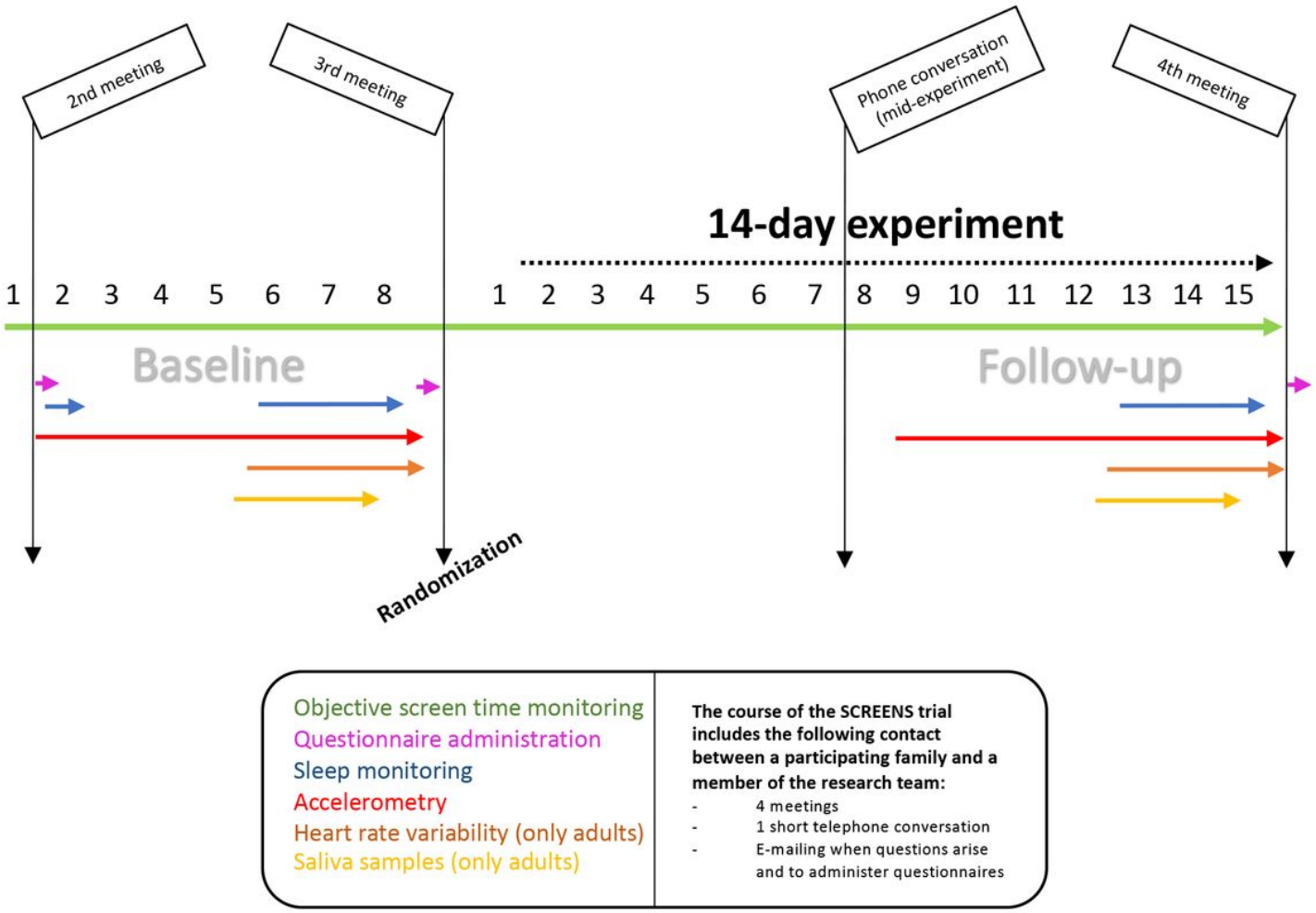

Figure 1

Meeting and measurement protocol The figure above illustrates the structure of the SCREENS trial in days regarding scheduled meetings, as well as the timing of exposure and outcome measurements. The program is structured such that baseline and follow-up commence on the same day of the week, so the data will be collected on the same days. Note that the only difference between baseline and follow-up is that at baseline a test sleep measurement is included during the first night. The 1st meeting (not shown above) is a mandatory information meeting, prior to the trial. The figure above is re-used from an earlier publication (see acknowledgements).

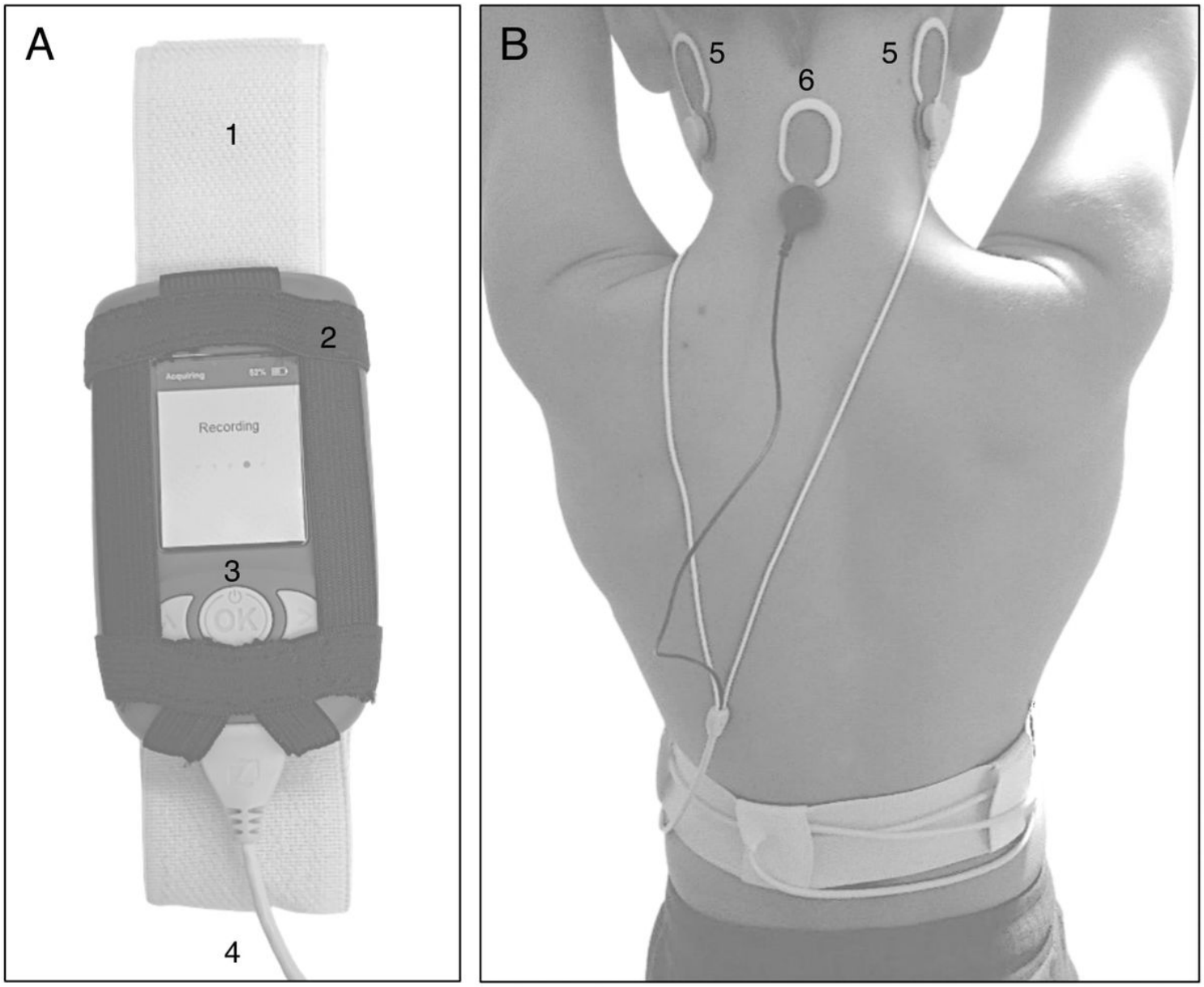

Figure 2

Sleep assessment set-up Image A shows the elastic belt (1), the custom-made elastic pocket (2), the Zmachine (3) and the cable from the Zmachine (4). Image B shows the signal sensors at the differential mastoids (5) and the ground sensor on the middle of the neck (6).

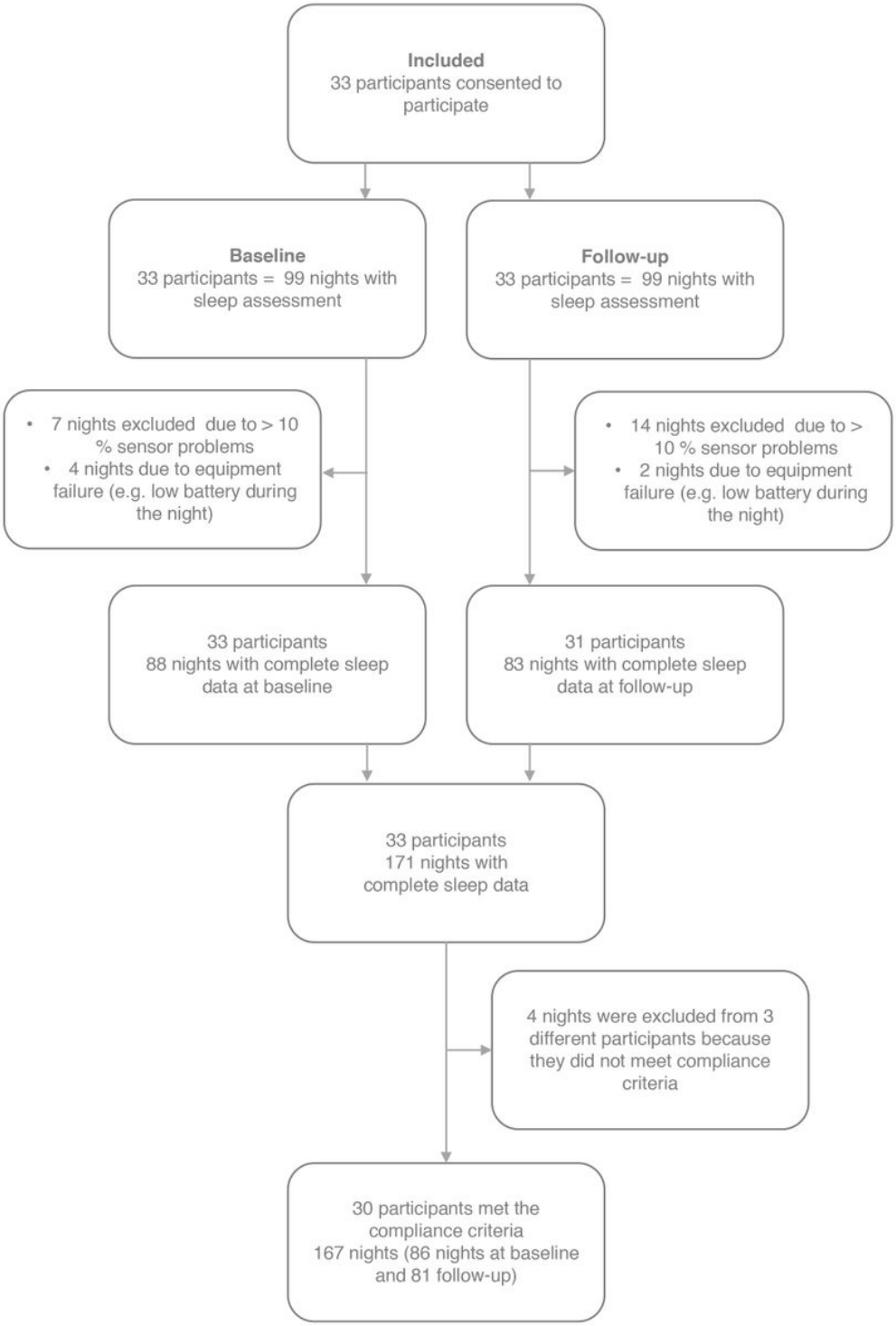

Figure 3

Flow of participants from inclusion to compliant participants. The figure above shows the flow of participants from inclusion to compliant participants. The number of nights with complete sleep data is also shown at each stage.

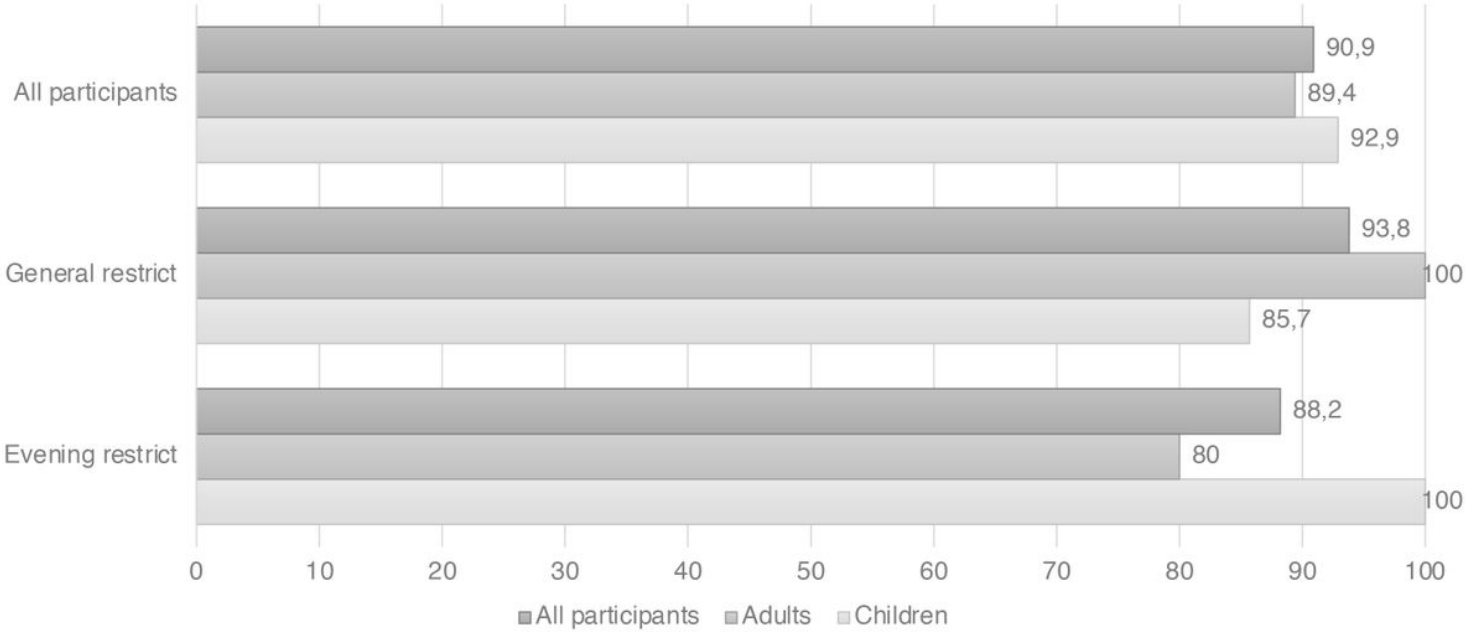

Figure 4

Proportion of compliant participants The figure above illustrates the proportion of participants who were compliant to the sleep assessment protocol. Results are shown for all participants and for each intervention group.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile3.docx
- Additionalfile2.docx
- Additionalfile1.pdf