Sustainable Habits for Encouraging Even Teen Sleep (SHEETS): A Digital Intervention to Enhance Sleep and Psychiatric Health in Adolescents

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Duke University Health System

Consent To Participate In A Research Study
Sustainable Habits for Encouraging Even Teen Sleep (SHEETS): A Digital Intervention to Enhance Sleep and Psychiatric Health in Adolescents
Pro00109013

Sponsor: National Institutes of Health (NIH)

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CONCISE SUMMARY

The purpose of this research study is to evaluate a 6-week digital sleep intervention to promote healthy sleep patterns.

You and your child will be asked to come to 4 different study visits: baseline, post-intervention, 3 month and 6 month follow up. You and your child will be asked to complete questionnaires about demographics, psychiatric health, and sleep patterns. Your child will be asked to wear an ActiGraph watch for 24hrs/day for a week for 4 separate weeks, a Garmin for the duration of the 6-week intervention and keep a sleep diary through an online program.

The potential risks associated with participating in this study include frustration from completing questionnaires, possible discomfort answering questions, and loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

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You and your child are being asked to take part in a research study in the Department of Psychiatry at Duke University Medical Center. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the principal investigator or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide if your child will take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the principal investigator or study staff if your child is taking part in another research study.

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Drs. Jessica Lunsford-Avery's, Naomi Duke's and their research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you allow your child to participate, Drs. Jessica Lunsford-Avery, Ph.D., a clinical psychologist and Naomi Duke, M.D., PhD, a pediatrician will be the principal investigators conducting the study. The principal investigators may be in contact with your child's regular health care provider throughout the time that they are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to see if a 6-week digital sleep intervention (SHEETS) is accepted by adolescents and if it is effective in promoting healthy sleep patterns. Additionally, we will try to determine if any improved sleep patterns experienced from the intervention are linked to improved psychiatric health.

HOW MANY WILL TAKE PART IN THIS STUDY?
Approximately 50 adolescents will take part at Duke. Duke may need to screen up to 75 potential participants to get 50 eligible participants. If we have participants who are withdrawn from the study early, we plan to replace them.

WHAT IS INVOLVED IN THE STUDY?
If you agree to allow your child to be in this study, you and your child will be asked to sign and date this consent form. You will be given a copy of this signed and dated consent form. Only one child per family will be recruited into this study.

You and your child's participation will include the following:

Sleep Intervention

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Intake Visit:
You/your child will be asked to come to an onsite intake visit. During this visit your child will complete a series of questionnaires electronically and will include:

- demographics (e.g. age, race-ethnic self-identification, receipt of free or reduced-price lunch),
- academic achievement, school and community activity involvement,
- material stresses (e.g. food insecurity, housing instability),
- family roles and responsibilities,
- neighborhood safety and cohesion,
- experiences of bullying and harassment,
- mental health indicators (e.g. anxiety, mood, attention, psychosocial functioning),
- health and risk behaviors,
- self-efficacy,
- behavioral intentions,
- medical history including medications,
- vital signs (waist circumference, height, weight, blood pressure, and resting pulse),
- device tolerability,
- pubertal self-assessment,
- and sleep practices, disturbances, and daytime sleepiness

You will also be asked to complete a parent/guardian questionnaire including demographic information, household and family experiences, mental health indicators, and your confidence in your ability to support your child's sleep behavior change. You will also be asked about your own sleep behaviors.

Baseline 7-day sleep assessment:
After the intake visit, your child will be asked to wear an ActiGraph and Garmin device on their non-dominant wrist for 24 hours/day for a 7-day period. They will also be asked to complete a daily, electronic Sleep Diary. After the 7th night, we will ask you to return the ActiGraph to the research clinic in person or via postage provided mail if you prefer. Your child will keep the Garmin to wear for the duration of the study.

Randomization:
Following the baseline assessment, your child will be randomly assigned (like the flip of a coin) to participate in one of two digital sleep interventions. You/your child will not be told which sleep intervention they will be participating in.

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Sleep intervention:
Your child will be asked to participate in one of two 6-week interventions targeting sleep health. These interventions will use a digital, web-based program (Pattern Health) to provide weekly activities regarding sleep education, common disruptors to sleep, sleep schedules, and behavior change tools. In addition, the platform will prompt your child to keep sleep journals and complete brief questionnaires regarding sleep. Pattern Health will also collect information from the Garmin such as heart rate and movement/rest patterns and communicate aspects of this information through the platform. Your child will receive messages nightly over the course of the 6-week intervention to remind them about preparing for sleep. Your child may be asked to interact with Dr. Lunsford-Avery, Dr. Duke, or a member of the study team using a secure chat function of the platform at a scheduled time to discuss their sleep health or practices.

In addition, you will receive weekly messages with strategies on how to support your child's sleep health through the platform.

Post-Intervention Assessment Visit: Your child will be asked to come back for an onsite, post-intervention visit. Vital signs and medical history including medications will be collected. They will complete a brief series of questionnaires. All questionnaire data will be collected electronically and will include: mental health and psychosocial functioning, self-efficacy, behavioral intentions, pubertal self-assessment, intervention satisfaction and acceptability, and device tolerability. They will repeat the sleep assessments conducted at the 7-day baseline assessment (see above).

You will also be asked to complete a brief questionnaire about your child's mental health indicators. You will also be asked about your own sleep.

After the Post-Intervention Assessment, your child will continue to wear the Garmin. Your child will participate in 3 monthly booster activities that will reinforce sleep health content learned during the sleep intervention.

3 Month Follow-up Assessment Visit: Three months after the Post-Intervention visit, your child will have an onsite follow-up visit, in which vital signs and medical history including medications will be collected, and they will complete another series of questionnaires. These will include: demographics, mental health indicators (e.g. internalizing and externalizing symptoms, psychosocial functioning), health and risk behaviors, self-efficacy, behavioral intentions and pubertal self-assessment. They will repeat the sleep assessments described above in the baseline assessment.

You will also be asked to complete a brief questionnaire about your child's mental health indicators. You will also be asked about your own sleep.

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6 Month Follow-up Assessment Visit: Six months after the Post-Intervention visit, your child will have an onsite follow-up visit, in which vital signs and medical history including medications will be collected, and they will complete another series of questionnaires. These will include: demographics, academic achievement, school and community activity involvement, material stresses, family roles and responsibilities, neighborhood safety and cohesion, experiences of bullying and harassment, mental health indicators (e.g. internalizing and externalizing symptoms, psychosocial functioning), health and risk behaviors, self-efficacy, behavioral intentions, and pubertal self-assessment. They will repeat the sleep assessments described above in the baseline assessment.

You will also be asked to complete a brief questionnaire about your child's mental health indicators. You will also be asked about your own sleep.

WHAT WILL MY CHILD BE ASKED TO DO IN THIS STUDY?
Before you decide whether to allow your child to be in this study, you should think about how the tests and study visits will affect your time away from work, your child's school and related activities, and your schedule.

To be in this study, you and your child must agree to:

- Follow directions from the study staff
- Make and keep study appointments
- Use the actigraph and sleep diary as directed
- Use the app platform as directed
- Not be part of any other research study while participating in this study
- Not allow anyone else to use the actigraph,Garmin, or app platform

Use of medications for sleep (prescription or over-the-counter) are not permitted during the study. The study team will tell you which medications are not allowed and which are allowed to be taken by your child during this study.

HOW LONG WILL MY CHILD BE IN THIS STUDY?
You and your child will be in this study for approximately 8 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you and your child are entitled.

WHAT ARE THE RISKS OF THE STUDY?
It is possible that you and your child may experience frustration from the inconvenience of spending time completing questionnaires. There is a risk of discomfort or distress answering some questions. You and your child may refuse to answer any questions while completing the questionnaires. You may stop your and your child's participation in this study at any time.

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Some questionnaires will ask specifically about thoughts of self-harm and harm to others. If your child is at risk for either of these things, the study team will have a senior staff member, qualified to work in these situations, work with you (as the parent/guardian) and your child. If your child is at imminent risk of harm to self or others, you and your child will be withdrawn from the study and referred to the Duke University Medical Center Emergency Room for evaluation. If your child is at low/moderate risk, the staff will discuss treatment options and available resources for you and your child.

Actigraphy is a noninvasive, painless test. There are no known risks associated with actigraphy.

There is the potential risk of loss of confidentiality. Every effort will be made to keep your/your child's information confidential, however, this cannot be guaranteed.
There may be risks, discomfort, or side effects that are not yet known.

WHAT IF NEW INFORMATION BECOMES AVAILABLE?
We will tell you about new information that may affect your child's health, welfare or willingness to stay in the study. If you decide to continue your child's participation, you may be asked to sign a new consent form.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?
If you and your child agree to take part in this study, there may not be direct medical benefit to your child. We hope that the sleep interventions help promote healthy sleep patterns, but cannot say if that will be the case.

WILL MY CHILD'S INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about your child is kept confidential, but we cannot guarantee total confidentiality. Your child's personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your child's personal information may also be given out if required by law.

As part of the study, results of your child's study assessments and laboratory tests may be reported to the National Institutes of Health and its affiliates. Data may be stored and shared for future research without additional informed consent if identifiable private information, such as your child's name and medical record number, are removed. If your child's identifying information is removed from your child's samples or data, we will no longer be able to identify and destroy them. All of the individual participant data collected during the trial (including data dictionaries) will be available for this study after deidentification, as will the Study Protocol. This data will be available immediately following

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publication with no end date, and will be accessible by researchers who provide a methodologically sound proposal to achieve aims in the approved proposal. Data are available at the National Institute of Mental Health Data Archive (https://nda.nih.gov/). In addition, your child's records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of the National Institutes of Health, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your child's research record, they may also need to review your child's entire medical record.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your child's privacy. With this Certificate, the investigators may not disclose research information that may identify your child in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your child's medical treatment; or
3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your child's involvement in this research. If you want your child's research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to your child or others. Additionally, if the research team has reasonable cause to suspect abuse or neglect of a child, they are obligated to report this to the Department of Social Services.

All of the assessments and laboratory tests are being done only because your child is in this study. The study results will not be provided to you OR sent to your child's physician.

The study results will be retained in your child's research record for six years after the study is completed or until your child reaches the age of 21, whichever is longer. At that time either the research

information not already in your child's medical record will be destroyed or information identifying your child will be removed from such study results at DUHS.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your child's name or other personal information will not be revealed. Some people or groups who receive your child's health information might not have to follow the same privacy rules. Once your child's information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share your child's private information with anyone not involved in the study, the federal law designed to protect your child's health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?
There is no financial cost associated with participation is this sleep intervention study, except those associated with travel to the interview/onsite visits**.**

Your child will be provided with the ActiGraph device and Garmin free of charge for her/his use in this study and may keep the Garmin when the study is complete.

WHAT ABOUT COMPENSATION?
You will be reimbursed up to $280 for your expenses related to your child's participation to cover your parking, gas, and time. The compensation will be as follows:

- $30 for each onsite study visit (Baseline and 3 Follow Up visits)
- $40 per week (for each of 4 weeks) of wearing the actigraph and completing the sleep assessments

Your child will be allowed to keep the Garmin watch used for the study.

As an incentive to encourage engagement with the app, your child may be entered into a raffle for a $50 gift card if they complete all tasks within the app.

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If your child does not complete the study, you will receive compensation for the parts of the study that they completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that your child is injured as a result of his/her participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Lunsford-Avery at (919-681-0035) or Dr. Duke at 919-620-5333 during regular business hours and at 919-206-9154 (Lunsford-Avery) or 919-970-7578 (Duke) after hours and on weekends and holidays.

WHAT ABOUT MY CHILD'S RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose for your child not to be in the study, or, if you agree for them to be in the study, you may withdraw your child from the study at any time. If you withdraw your child from the study, no new data about your child will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your child's entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.

Your decision for your child not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Lunsford-Avery in writing and let her know that you are withdrawing from the study. Her mailing address is 2400 Pratt Street, North Pavilion Office 7036, Durham, NC 27705.

The investigators or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include:

- if your child needs a treatment not allowed in this study,
- if you and your child do not follow the study procedures as instructed,
- if the study is canceled by the sponsor.

The sponsor or the IRB may decide to stop the study at any time.

If this occurs, you will be notified and the study team will discuss other options with you.

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A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you or your child. At most, the Website will include a summary of the results. You can search this Website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Lunsford-Avery at (919-681-0035) or Dr. Duke at 919-620-5333 during regular business hours and at 919-206-9154 (Lunsford-Avery) or 919-970-7578 (Duke) after hours and on weekends and holidays.
Unencrypted Communication:
Because (e-mail/text/etc.) does not provide a completely secure and confidential means of communication, please do not use email or texting if you wish to keep your communication private. Instead, please let us know and we will communicate with you only through regular channels like the telephone.

For questions about your child's rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

Parent/Guardian Initials: _____

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to my child and me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree for my child to be in this study, with the understanding that I may withdraw my child at any time. We have discussed the study with my child, who agrees to be in the study. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Parent or Legal Guardian	Date	Time
Signature of Parent or Legal Guardian	Date	Time
Signature of Child (if age 12 or over)	Date	Time
Signature of Person Obtaining Consent	Date	Time