Official Title:

Preschool Attention and Sleep Support (PASS): A Telehealth Intervention for Children at Risk for ADHD

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Duke University Health System

Consent to Participate in a Research Study
PASS: A Telehealth Intervention for Children with Attentional and Behavioral Concerns

TITLE: PASS: A Telehealth Intervention for Children with Attentional and Behavioral Concerns
SPONSOR: National Institutes of Health (NIH)
PRINCIPAL INVESTIGATOR: Jessica Lunsford-Avery, PhD
STUDY RELATED PHONE NUMBERS:
Daytime Telephone Number: (919) 681-0035
24-hour Contact Number: (919) 206-9154

KEY INFORMATION SUMMARY

The purpose of this study is to evaluate a 9-week telehealth intervention for preschoolers with attentional or behavioral concerns.

Participant's guardians will be randomly assigned (like the flip of a coin) to participate in one of two 9-week telehealth interventions for preschool children with attentional or behavioral concerns. Participants and their guardians will also attend three study visits (one baseline, and two follow up visits) where they will be asked to complete questionnaires and assessments related to their attentional or behavioral concerns , psychiatric health, and sleep habits. Following each study visit, child participants will be asked to wear an ActiGraph device (similar to a wrist watch) on their nondominant wrist for 24 hours/day for a 7-day period. Participant's guardians will also be asked to complete an electronic daily diary about their child's sleep.

The potential risks associated with participating in this study include frustration from completing questionnaires, possible discomfort answering questions, and loss of confidentiality. We don't know if there is a direct benefit, but we hope that the 9-week intervention provides parents with skills to address their child's attentional or behavior-related symptoms. However, we cannot guarantee that will be the case.

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

You and your child are being asked to participate in this research study because your child is between the ages of 3-5 with attentional or behavioral concerns. Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below and will be reviewed with you by the study team.

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

Dr. Jessica Lunsford-Avery will conduct the study. The study is funded by a grant from the National Institutes of Health. Portions of Dr. Jessica Lunsford-Avery's and her research team's salaries will be paid by this grant.

Who will be my child's doctor on this study?
If you decide to have your child participate, Dr. Jessica Lunsford-Avery will be your child's doctor for the study and will be in contact with your child's regular health care provider throughout the time that your child is in the study and afterwards, if needed.

Why is this study being done?
The purpose of this study is to evaluate a 9-week telehealth intervention for preschoolers with attentional and behavioral concerns.

How many people will take part in this study?
Up to 62 ~~44~~ children and their caregivers will take part in this study.

What is involved in the study?
If you agree to allow you and your child to be in this study, you will be asked to sign and date this consent form, and will be given a signed and dated copy. This study consists of three study visits (one baseline visit, and two follow up visits), three 7-day activity and sleep assessments, and a 9-week telehealth intervention targeting attentional and behavioral concerns.

Screening/Baseline Visit
You and your child will be asked to attend an initial in-person screening visit where we will assess your child's attention and behavior, sleep habits, and medical history to confirm that you and your child qualify for the study. If you and your child qualify, you will be asked to complete additional questionnaires and assessments about your child's behavior, attention, and psychiatric health, as well as your own psychiatric health, sleep habits and parenting experiences. This visit will last around 2 hours.

7-day activity and sleep assessment
Following each study visit, your child will be asked to wear an ActiGraph device (similar to a wrist watch) on their nondominant wrist for 24 hours/day for a 7-day period. You will also be asked to complete an electronic daily diary about your child's activity, sleep, and mood. During this time, we ask that you and your child adhere to your regular schedule as much as possible (i.e., no travel or vacations). At the end of the 7-day period, we will ask you to return the ActiGraph device to the study team in-person or via mail.

Telehealth intervention:
You will be randomly assigned (like the flip of a coin) to participate in one of two telehealth interventions for preschool children with attentional or behavior concerns. You/your child will not be

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told which intervention you will be participating in. The intervention will consist of nine weekly sessions conducted by a behavioral health practitioner. Both interventions will teach you evidence-based skills and provide practice opportunities to manage your child's attentional and behavioral concerns. The sessions will be conducted virtually over Zoom.

Follow up visits
You and your child will be asked to complete two in-person follow up visits – one immediately following the telehealth intervention, and one after three months. During these visits, you will be asked to complete questionnaires and assessments related to your child's attentional or behavioral concerns, psychiatric health, and sleep habits, as well as your own psychiatric health, sleep habits, and parenting experiences. Your child will also be asked to complete another 7-day activity and sleep assessment after each visit, following the same procedures as outlined above.

How long will my child be in this study?
You and your child will be in this study for approximately 5 months. You and your child can choose to stop participating at any time without penalty. However, if you and your child decide to stop participating in the study, we encourage you to talk to your child's doctor first.

What are the risks of the study?
There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. 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.

Actigraphy is a noninvasive, painless assessment. The primary risk associated with wearing the ActiGraph watch is discomfort.

There may be risks, discomfort, or side effects that are not yet known.

Are there benefits to taking part in the study?
If you agree for your child to take part in this study, we do not know if there is a direct benefit. We hope that the 9-week intervention provides skills to address your child's attentional or behavioral concerns , however, we cannot guarantee that will be the case.

Will my and 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 you/your child is kept confidential, but we cannot guarantee total confidentiality. Your/ 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

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the minimum necessary information in order to conduct the research. Your/ your child's personal information may also be given out if required by law.

As part of the study, results of any study-related tests or procedures may be shared with the NIH and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- Representatives and affiliates of the NIH,
- The Duke University Health System Institutional Review Board,
- And others as appropriate.

If any of these groups review your research record, they may also need to review your entire medical record.

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

The study results will be retained in your/ 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 or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer 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 name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain confidential. If you decide to share your information with anyone not involved in the study, the federal law designed to protect your 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.

This National Institutes of Health (NIH) has issued a Certificate of Confidentiality (CoC) for this study. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or lawsuit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings, like a court order.

There are some important things that you need to know about the CoC:

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It DOES NOT stop reporting required by federal, state or local laws. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others.

It CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs, including when the Food and Drug Administration (FDA) requires it.

It DOES NOT prevent your information from being used for other research if allowed by federal law.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other people not connected with the study. The CoC does not stop you from willingly releasing information about your involvement in this study. It also does not prevent you from having access to your own information.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself 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.

What are the costs to you?
There is no cost for being in the study, except those associated with travel to the onsite visits**.** However, parking vouchers will be given to participants who attend onsite visits.

What about compensation?
You will be compensated up to $240for your participation: :

- $40 for attending each study visit (screening/baseline, follow-up, 3 month follow-up)
- $40 for completing each 7-day ActiGraph assessment

You will only be paid for the visits you complete. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study

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 child's Duke physicians to provide monetary compensation or free medical care to your child in the event of a study-related injury.

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

What about my rights to decline participation or withdraw from the study?
You may choose not to allow your child to be in the study, or, if you agree to allow your child to be in the study, you may withdraw 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 other than data needed to keep track of your child's withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you/your child are entitled, and will not affect your or your child's access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Jessica Lunsford-Avery in writing and let her know that you are withdrawing from the study. Her mailing address is 2400 Pratt St. Rm. 7036, Durham, NC, 27705. You will be asked to return the ActiGraph device to the study team via a pre-paid mailer. She may also ask your child to complete the tests that would ordinarily occur when a person completes the study.

We will tell you and your child about new information that may affect your child's health, welfare, or willingness to stay in this study. 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 or IRB.

If this occurs, you will be notified and your child's study doctor will discuss other options with you and your child.

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 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/). For this study, a unique identification number (Global Unique Identification, or GUID) will be created for you. This number will be used to connect (link) your research information from this study to other research studies that you may participate in that also use the GUID system. To receive this number, you and a

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study staff member will go to a secure internet website on a computer at the research clinic and enter information about you: your first, middle and last names at birth, any suffixes (Jr., III, etc.), your date of birth, name of the city where you were born, and your country of birth. Once the GUID is created, your personal information is deleted.

The use of your/ your child's data may result in commercial profit. You and your child will not be compensated for the use of the data and samples other than what is described in this consent form.

A description of this clinical trial will be available on https://www.clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you or your child. At most, the Web site will include a summary of the results. You can search this Web site 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. Jessica Lunsford-Avery at (919) 681-0035 during regular business hours and at (919) 206-9154 after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have questions about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to 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 me and my child to be in this study, with the understanding that I may withdraw myself and my child at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Parent/Guardian	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time