Reducing Challenging Behaviors in Children With Autism Through Digital Health

(1) Parent Informed Consent & HIPAA Authorization Form

(2) Teacher Informed Consent & HIPAA Authorization Form

NCT05277194

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University of Pennsylvania
Parent Informed Consent Form and HIPAA Authorization Form

Development of a Digital Biosensor Stress Alarm for School-Aged Students with Autism
KeepCalm App Development Study
Randomized Controlled Trial (Phase 3)

Protocol Title: KeepCalm App Development Study
Principal Investigator: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu.
Emergency Contact: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu.
Sponsor: National Institute of Mental Health

Research Study Summary for Potential Subjects

You and your child are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the research team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to trial the smart phone application, the KeepCalm app, to understand how easy it is to use, whether it is a good fit for students on the autism spectrum, and whether it is feasible to use it in the classroom setting for helping teachers know when and how to intervene on children's challenging behaviors and support their emotion regulation development.

If you agree to join the study, you will be asked to 1) attend an intake meeting; 2) attend an app training meeting (school personnel only); 3) record the child's baseline heart rate using a wrist-band or chest-strap heart rate tracker (school personnel only); 4) have the child wear the heart rate and movement trackers at school for three months (school personnel only); 5) use the app during this three-month testing period to track children's triggers/antecedents, challenging behaviors/skills and intervention strategies and use other app features* (school personnel only);
6) view the child daily summaries and send morning notes to teachers when appropriate and use other app features* (parents only); 7) provide app feedback in a 30-minute interview following the trial; 8) complete surveys; and 9) allow access to the child's Individualized Education Program (IEP) and/or behavioral plans, if required.

*Other app features available to parent participants are the child data figures/reports, the intervention strategies resources, and the team messaging feature.

Your participation in the trial will last for three months. During this time, the app will be available for your viewing and use, and we encourage you to explore and utilize the app's features. Your participation will also include an intake interview expected to take approximately 30-45 minutes and a feedback interview expected to take 45-60 minutes.

There are no direct benefits to you for participating in this study. However, this study is expected to improve our understanding of how to monitor and minimize stress in children with autism. We do not anticipate any significant risks of participation. The most common risks of participation are experiencing discomfort in talking about your experiences and emotions during the post-trial interview. You may also feel discomfort being video/audio-recorded during the interview. Children may experience discomfort wearing the heart rate/movement tracker.

Your alternative to participation is not participating in the study at all. The decision is yours to make and will not affect your relationship with the school district, the University of Pennsylvania, or the research team.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed below. If you are interested in participating, you may read on to acquire the full information. You are free to decline or stop participation at any time during or after the initial consenting process.

Would you like to continue? [Yes] [No]

Why am I being asked to be a

volunteer?

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and you will be able to download a copy, or it can be emailed or mailed to you. Keep this form, for in it you will find contact information and answers to questions about the study.

You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to test a smart phone application, the KeepCalm app, for educational teams to help them to know when and how to intervene to support students on the autism spectrum develop emotion regulation skills and to manage their challenging behaviors at school. Parents have access to the application to view day reports on their child's triggers and behaviors and top strategies to use with them. The app can be used by both teachers and parents to learn about evidence-based strategies and to communicate about students to ensure consistency in approaches to supporting emotion regulation and managing challenging behaviors across home and school. The app incorporates wearable trackers to measure children's heart rate (children can choose a chest-strap or wristband model) and movement (a belt clip), which connect via Bluetooth to the KeepCalm app.

The research team has completed the first two out of the three phases of the study: 1) gaining ideas from parents, children with autism, teachers, and school-administrators on how to best design the app and 2) testing how easy it is to use the app at school and using teacher feedback to further improve the app. In the third phase of the study, this phase, we are conducting a pilot trial of the finalized app in autism support classrooms.

Why was I asked to participate in this study?

You are being asked to join this study because you are the parent or guardian of a preschool student or elementary school-age student with autism. Your child with autism is between the ages of 3-12 years old and exhibits challenging behaviors (i.e., aggression, escape behavior, loud noises, non-compliance, rigid/inflexible behavior, etc.).

How long will I be in the study? How many other people will be in the study?

We will recruit participants in 20 education teams, each including a teacher, 1-2 students on the autism spectrum in their classroom, their 1:1/aide (if they have one and they are interested in participating), and their parent(s). The teams will be randomized into one of two groups:

- Group 1 will use the app immediately for 3 consecutive months, and
- Group 2 will be placed on the waitlist to use the app following the first group's completion of their trial (i.e., after 3 months)

Therefore, each individual participant will participate in the testing of the app for 3 consecutive months and people in the Group 2 will commence this after a 3-month waiting period.

Where will the study take place?

The research will take place at the home and school of the students with autism and virtually, via video conference meetings.

What will I be asked to do?

To participate in this study, you must complete the consent process. The consent process requires you to review and sign this consent form. If you decide to participate, we will ask you to:

1) Attend an intake meeting once your team has signed up (one parent, one child, and one teacher at a minimum) held virtually and/or at the child's preschool, school, home, or another preferred location. During this session, participants will be individually briefed on the KeepCalm app and baseline assessments will be completed. Parents will be asked to complete a 10-minute demographic survey. Children will be asked to complete several assessments expected to take approximately one hour and 10 minutes. This may include a standardized child cognitive assessment if not previously conducted/if scores are unavailable.

2) Before app testing, school personnel will participate in an app training session held virtually and/or at the child's preschool or school and will be given access to the app and the heart rate and movement trackers.

3) School personnel participants will then record at least one baseline heart rate of the child to calibrate the app's stress zone notification to that child. This will be done over a 5- minute period using a wristband or chest-strap heart rate monitor (whichever the child prefers) in which the child is engaged in an activity that is relaxing to them that does not involve much movement (e.g., story reading).

4) Students with autism will wear the heart rate tracker (wristband or chest-strap, whichever they prefer) and movement tracker (belt-clip) to the extent they are able to throughout the school day, each school day throughout the three-month testing period. If a device is uncomfortable for a participant, it can be simply taken off.

5) School personnel will use the app with the child each school day during the three-month app testing period. This may include tracking the student's heart rate and movement, entering child data (triggers/antecedents, challenging behaviors/skills, and intervention strategies), referencing the daily report, using and exporting the child data figures, accessing and using the intervention strategies resources embedded in the app, and/or using the team messaging feature including sending the student's parent afternoon notes. Depending on safety protocols and preferences at the time of this phase of the study, in- person observations by researchers may be also conducted. The research team will also monitor remotely each team's usage of the app during their respective testing period and message the team on a weekly basis ask if any adverse events have arisen. The initial app version is for iPhones; if you do not have an iPhone, then one will be loaned to you for the trial.

6) Parents will also use the app during the three-month app testing period. This may include receiving the auto-generated daily report based on the data your child's team enters each school day, using and exporting the child data figures, accessing and using the intervention strategies resources embedded in the app, and/or using the team messaging feature including sending your child's teacher morning notes. The initial app version is for iPhones; if you do not have an iPhone, then one will be loaned to you for the trial.

7) After app testing has been completed, both school personnel and parents will be asked to provide feedback to the research team regarding your experience with the app through a 45–60-minute interview with a member of the research team.

8) Teachers and parents will be asked to complete a survey about your experience using the KeepCalm app and the behaviors of the student with autism, which is expected to take approximately 30 minutes total and will be completed in the middle and at the end of the trial.

9) Allow the research team to have access to your child's Individualized Education Program (IEP) and behavioral plans, if required, for individualizing the app for the child with autism or obtaining past child standardized cognitive assessment scores.

By signing this consent, I agree to these meetings being video and/or audio recorded for team training and/or transcription purposes. Video and audio files will be stored on a password-protected and HIPAA compliant server and will only be accessible by the research team who have each completed HIPAA training.

What are the risks of participating in the study?

You may experience discomfort in talking about your experiences and emotions as part of the discussions throughout the trial. You may feel discomfort being video/audio-recorded during your interview. Children may experience some discomfort from wearing the heart rate or movement tracker. Children will be able to choose the device they feel most comfortable in; for the heart rate tracker, wristband and chest-strap versions will be available. Children will be asked to wear the device throughout the day. If the device is uncomfortable to the child, they can simply take it off. Additionally, wearing a heart rate tracker may identify the child as someone participating in a study.

How will I benefit from participating in the study?

You will be compensated a total of $150 for participating in all study activities ($50 paid at three measurement timepoints). There are no other direct benefits to you for participating in this study. However, this study is expected to improve our understanding of how to monitor and minimize stress in children with autism.

What other choices do I have?

Your alternative to being in the study is to not be in the study. Not participating in the study will not affect you, nor will it affect you or your child's access to any services in any way.

What happens if I choose not to join the research study?

You may choose to join the study, or you may choose not to join the study. If after beginning the study, you decide not to continue your participation, you may choose to stop participating at any time. Your participation is voluntary.

Your decision on whether or not to participate in this research will not affect your relationship with the University of Pennsylvania or your child's preschool or school, and related services or, for parent participants, any other service your child receives. You can end your participation at any time. We can stop the session at any point if you feel uncomfortable.

When is the study over? Can I leave the study before it ends?

The study is expected to end in 2024, though your participation will end after your three-month long app testing period and completing all measures and meetings with the research team. The study may be stopped without your consent for the following reasons:

- The Principal Investigator feels it is best for your safety or the safety of the child. You will be informed of the reasons why.
- The Principal Investigator, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

You may drop out of the study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will have no bearing on you/your child's services or relationship with the University of Pennsylvania or your child's preschool or school.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely finished.

If you no longer wish to be in the research study, please contact the Principal Investigator, Heather Nuske, PhD, at (215) 746-6041. You can withdraw from the study by verbally stating that you do not wish to participate in the KeepCalm App Development Study. Clearly state your name and address and a written verification of your removal from the study will be sent to you within 30 calendar days. Alternatively, if you would prefer to provide written notification of withdrawal you may send this information to:

Dr. Heather Nuske
Penn Center for Mental Health

Department of Psychiatry
Perelman School of Medicine
3535 Market Street, Floor 3
Philadelphia
PA 19104

How will my personal information be protected during the study?

All information you provide will be kept confidential, except as required by law. Confidentiality will have to be broken if you express a current plan to harm yourself or others, or if you report that you have committed child abuse or neglect. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. If information from this study is published or presented at scientific meetings, your name, your child's name, and other personal information will not be used. Confidentiality will be maintained through deidentifying any personal information obtained during the study, and only allowing access to such information to the research team. HIPAA guidelines will be followed (see more detail below).

What may happen to any identifiable information collected in this study?

In the KeepCalm app, the only identifiable health information of the child participation that will be entered will be their name or nickname entered by their teacher or parent and their heart rate data (as it will be linked with their name or nickname). The only identifiable information entered in the KeepCalm app for parent participants will be your first and last name, email, and phone number.

As part of the study, you will complete demographic surveys and we will ask about the child's behaviors and any medications they are taking as some medications are known to affect heart rate.

Following completion of the trial, all information you provide including information provided in the KeepCalm app will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within the University of Pennsylvania, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Will I receive the results of research testing that may be relevant to my health?

As the KeepCalm app will continually monitoring heart rate in children during app testing, it is possible the data collected could help to screen for heart rate or cardiac abnormalities in the children that may need to be followed up with their healthcare provider.

If your child has been found to have heart rate outside of the normal range for their age, you give permission for Dr. Nuske or a member of her research team to contact you via your preferred method of contact to communicate this information. You acknowledge that Dr. Nuske and her team would be able to share your child's heart rate but would be unable to provide diagnoses or opinions on the heart rate data, however these could then be followed up with your child's health care provider. Signing this consent form will give permission to Dr. Nuske or a member of her research team to contact you about any identified heart rate abnormalities in your child if they are found. If your child has a normal heart rate for their age, no follow-up communication will be necessary.

What happens if I am injured from being in the study?

If you are injured or feel emotional discomfort while participating in the study, you may contact the Principal Investigator or the emergency contact name on the first page of this form. They can go over procedures with you, share resources that may be available, and give you information on how to proceed. In case of injury resulting from this study, you will not lose any legal rights by signing this form. Also, you may contact your own doctor, counselor, or seek treatment outside of the University of Pennsylvania. Bring this document and tell your doctor/counselor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the numbers on the first page of this form for information.

If you are injured or feel emotional discomfort from being in the study, the appropriate care will be provided without cost to you through the University of Pennsylvania, but financial compensation is not otherwise available from the University of Pennsylvania. If you are injured or feel emotional discomfort while in the study but it is <u>not related</u> to the study, you and your insurance company will be responsible for the costs of that care.

Will I have to pay for anything?

There are no costs associated with participating in this study, beyond your time to complete the consent process, app-testing, interview, and survey.

The following section relates to your personal information and the health information of your child collected as part of the study

What personal information about me or my child may be collected, used, or shared with others?

In the KeepCalm app, children's heart rate will be monitored using a wearable heart rate tracker. In order to create an account in the app, we will ask your name, email, and telephone number. Your child's study ID instead of their name will be entered in the app. As part of your participation in the study through online surveys or in meetings, we will ask your name, address, telephone number, date of birth, Social Security Number, personal and family medical history, and we will ask about the medications your child is currently taking as some medications affect heart rate.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information is used to:

- conduct the research
- oversee the research
- ensure the research was done correctly
- to evaluate and manage research functions

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information will be stored in other HIPAA-compliant research databases and servers and data entered into the KeepCalm app will be stored in a custom-built server housed at Penn Medicine. With regards to security, the KeepCalm app uses Amazon Cognito, which requires multi factor authentication for all users. All data are encrypted in transit via HTTPS/SSL/TLS.

Who may use and share health information about me?

- The Principal Investigator of the study, Dr. Nuske, and the research team
- Other members of the child's educational team including their parent, teacher and aide (data recorded into the KeepCalm app only)
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my personal health information?

- Those working under the direction of the Principal Investigator for the study, Dr. Nuske, including the app development team
- The funding sponsor, the National Institutes of Mental Health (NIMH), and organizations supporting the sponsor

<u>Oversight organizations</u>

- The U. S. Office of Human Research Protections (OHRP)

Once protected health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal information or the health information of my child?

Your authorization for use of your personal information or the health information of your child for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my or my child's information?

Yes. You may withdraw or take away your permission to use and disclose your information or your child's health information at any time. You do this by sending written notice to the investigator

for the study as described above. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my information or my child's personal health information?

Then you will not be able to be in this research study.

You will be given a copy of this Informed Consent Form and HIPAA Authorization Form describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you and where applicable your child for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns, or complaints regarding your participation in this research study, or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any questions, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

By signing this form, you are indicating that you have had your questions answered, you agree to take part in this research study, and that you are legally authorized to consent to your child's participation. You are also agreeing to let the University of Pennsylvania use and share your information and your child's health information, as explained above. If you don't agree to the data collection, use and sharing of your/your child's health information, you/your child cannot participate in this study.

Fill out the following information to indicate your consent to participate in this study:

First name: _____

Last name: _____

Date: _____/ _____/ _____

Signature: _____

- I would like a summary of the overall findings of this research project
- I am interested in being contacted about other studies at the University of Pennsylvania

Parent/Guardian Participants

I agree to take part in this research study with my child:

Child's first name: _____

Child's last name: _____

Child Participants: Assent to Take Part in this Research Study (optional)

Regarding your child's participation in the study, please explain this study and the procedures involved to your child in terms he/she can understand (e.g., wearing the gadget they find most comfortable to measure their heartbeat and movement) and choose the most appropriate response below.

Does your child assent to participating in the trial of the KeepCalm app?

- Yes (my child is capable of providing assent and has freely assented to take part in this study)
- No (my child is capable of providing assent and has decided NOT to take part in this study)
- My child is not capable of providing assent (parent has consented so they will take part in the study)

University of Pennsylvania
Teacher/Aides Informed Consent Form and HIPAA Authorization Form

Development of a Digital Biosensor Stress Alarm for School-Aged Students with Autism
KeepCalm App Development Study
Randomized Controlled Trial (Phase 3)

Protocol Title: KeepCalm App Development Study
Principal Investigator: Heather J. Nuske, PhD, 3535 Market St, 3rd Fl., Philadelphia PA 19104, (215) 746-6041, heather.nuske@pennmedicine.upenn.edu.
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Sponsor: National Institute of Mental Health

Research Study Summary for Potential Subjects

You and your student are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the research team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to trial the smart phone application, the KeepCalm app, to understand how easy it is to use, whether it is a good fit for students on the autism spectrum, and whether it is feasible to use it in the classroom setting for helping teachers know when and how to intervene on children's challenging behaviors and supporting their emotion regulation development.

If you agree to join the study, you will be asked to 1) attend an intake meeting; 2) attend an app training meeting (school personnel only); 3) record the child's baseline heart rate using a wrist-band or chest-strap heart rate tracker (school personnel only); 4) have the child wear the heart rate and movement trackers at school for three months (school personnel only); 5) use the app during this three-month testing period to track children's triggers/antecedents, challenging behaviors/skills and intervention strategies and use other app features* (school personnel only); 6) view the child daily summaries and send morning notes to teachers when appropriate and use other app features* (parents only); 7) provide app feedback in a 30-minute interview following the trial; 8) completing surveys; and 9) allow access to the students' students' Individualized Education Program (IEP) and/or behavioral plans, if required.

*Other app features available to both school personnel and parent participants are the child data figures/reports, the intervention strategies resources, and the team messaging feature.

Your participation in the trial will last for three months. During this time, we encourage you to use the app and its features with your participating student(s) during each school day. Your participation will also include an intake interview and a feedback interview each expected to take 45-60 minutes.

There are no direct benefits to you for participating in this study. However, this study is expected to improve our understanding of how to monitor and minimize stress in children with autism. We do not anticipate any significant risks of participation. The most common risks of participation are experiencing discomfort in talking about your experiences and emotions during the post-trial interview. You may also feel discomfort being video/audio-recorded during the interview. Children may experience discomfort wearing the heart rate/movement tracker.

Your alternative to participation is not participating in the study at all. The decision is yours to make and will not affect your relationship with the school district, the University of Pennsylvania, or the research team.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed below. If you are interested in participating, you may read on to the full information. You are free to decline or stop participation at any time during or after the initial consenting process.

Would you like to continue? [Yes] [No]

Why am I being asked to be a volunteer?

You are being asked to take part in a research study. Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and you will be able to download a copy, or it can be emailed or mailed to you. Keep this form, in it you will find contact information and answers to questions about the study.

You may ask to have this form read to you.

What is the purpose of the study?

The purpose of the study is to test a smart phone application, the KeepCalm app, for educational teams to help them to know when and how to intervene to support students on the autism spectrum develop emotion regulation skills and to manage their challenging behaviors at school. Parents also have access to the application to view day reports on their child's triggers, behaviors, and top strategies to use with them. The app can also be used by teachers and parents to learn about evidence-based strategies and to communicate about students to ensure consistency in approaches to supporting emotion regulation and managing challenging behaviors across home and school. The app incorporates wearable trackers to measure children's heart rate (children can choose a chest-strap or wristband model) and movement (a belt clip), which connect via Bluetooth to the KeepCalm app.

The research team has completed the first two out of the three phases of the study: 1) gaining ideas from parents, children with autism, teachers, and school-administrators on how to best design the app and 2) testing how easy it is to use the app at school and using teacher feedback to further improve the app. In the third phase of the study, this phase, we are conducting a pilot trial of the finalized app in autism support classrooms.

Why was I asked to participate in this study?

You are being asked to join this study because you work as a teacher or aide with preschool or elementary school-age students with autism. The students with autism you work with are between the ages of 3-12 years old and exhibit challenging behaviors (i.e., aggression, escape behavior, loud noises, non-compliance, rigid/inflexible behavior, etc.).

How long will I be in the study? How many other people will be in the study?

We will recruit participants in 20 education teams, each including a teacher, 1-2 students on the autism spectrum in their classroom, their 1:1/aide (if they have one and they are interested in participating), and their parent(s). The teams will be randomized into one of two groups:

- Group 1 will use the app immediately for 3 consecutive months, and
- Group 2 will be placed on the waitlist to use the app following the first group's completion of their trial (i.e., after 3 months)

Therefore, each individual participant will participate in the testing of the app for 3 consecutive months and people in the Group 2 will commence this after a 3-month waiting period.

Where will the study take place?

The research will take place at the home and school of the students with autism and virtually, via video conference meetings.

What will I be asked to do?

To participate in this study, you must complete the consent process. The consent process requires you to review and sign this consent form. If you decide to participate, we will ask you to:

1) Attend an intake meeting once your team has signed up (one parent, one child and one teacher at a minimum) held virtually and/or at the child's preschool, school, home, or another preferred location. During this session, participants will be individually briefed on the KeepCalm app and baseline assessments will be completed. Teachers will be asked to complete three surveys expected to take a total of 20 minutes, and children will be asked to complete several assessments expected to take approximately one hour and 10 minutes. This may include a standardized child cognitive assessment if not previously conducted/if scores are unavailable.

2) Before app testing, school personnel will participate in an app training session held virtually and/or at the child's preschool or school and will be given access to the app and the heart rate and movement trackers.

3) If teachers indicate they would like one (this is optional), they will attend a 1-hour info-session on evidence-based strategies for addressing challenging behaviors and supporting emotion regulation in students on the autism spectrum with a member of the research team over Zoom.

4) School personnel participants will then record at least one baseline heart rate of the child to calibrate the app's stress zone notification to that child. This will be done over a 5-minute period using a wristband or chest-strap heart rate monitor (whichever the child prefers) in which the child is engaged in an activity that is relaxing to them that does not involve much movement (e.g., story reading).

5) Students with autism will wear the heart rate tracker (wristband or chest-strap, whichever they prefer) and movement tracker (belt-clip) to the extent they are able to throughout the school day, each school day throughout the three-month testing period. If a device is uncomfortable for a participant, it can be simply taken off.

6) School personnel will use the app with the child each school day during the three-month app testing period. This may include tracking the student's heart rate and movement, entering child data (triggers/antecedents, challenging behaviors/skills, and intervention strategies), referencing the daily report, using, and exporting the child data figures, accessing and using the intervention strategies resources embedded in the app, and/or using the team messaging feature including sending the student's parent afternoon notes. Depending on safety protocols and preferences at the time of this phase of the study, in-person observations by researchers may be also conducted. The research team will also monitor remotely each team's usage of the app during their respective testing period and

message the team on a weekly basis ask if any adverse events have arisen. The initial app version is for iPhones; if you do not have an iPhone, then one will be loaned to you for the trial.

7) Parents will also use the app during the three-month app testing period. This may include receiving the auto-generated daily report based on the data their child's team enters each school day, using and exporting the child data figures, accessing and using the intervention strategies resources embedded in the app and/or using the team messaging feature including sending their child's teacher morning notes. The initial app version is for iPhones; if you do not have an iPhone, then one will be loaned to you for the trial.

8) After app testing has been completed, school personnel and parents will be asked to provide feedback to the research team regarding your experience with the app through a 45-60 minute interview with a member of the research team.

9) Teachers and parents will be asked to complete a survey about your experience using the KeepCalm app and the behaviors of the student with autism, which is expected to take approximately 30 minutes total and will be completed in the middle and at the end of the trial.

By signing this consent, I agree to these meetings being video and/or audio recorded for team training and/or transcription purposes. Video and audio files will be stored on a password-protected and HIPAA compliant server and will only be accessible by the research team who have each completed HIPAA training.

What are the risks of participating in the study?

You may experience discomfort in talking about your experiences and emotions as part of the discussions throughout the trial. You may feel discomfort being video/audio-recorded during your interview. Children may experience some discomfort from wearing the heart rate or movement tracker. Children will be able to choose the device they feel most comfortable in; for the heart rate tracker, wristband and chest-strap versions will be available. Children will be asked to wear the device throughout the day. If the device is uncomfortable to the child, they can simply take it off. Additionally, wearing a heart rate tracker may identify the child as someone participating in a study.

How will I benefit from the study?

You will be compensated a total of $150 for participating in all study activities ($50 paid at three measurement timepoints). There are no other direct benefits to you for participating in this study. However, this study is expected to improve our understanding of how to monitor and minimize stress in children with autism.

What other choices do I have?

Your alternative to being in the study is to not be in the study. Not participating in the study will not affect you, nor will it affect your access to any services in any way.

What happens if I choose not to join the research study?

You may choose to join the study, or you may choose not to join the study. If after beginning the study, you decide not to continue your participation, you may choose to stop participating at any time. Your participation is voluntary.

Your decision on whether or not to participate in this research will not affect your relationship with the University of Pennsylvania or your student's preschool or school, and related services. Your employment status as a teacher or 1:1 aide will not be affected by your decision to participate or not participate in this study. You can end your participation at any time. We can stop the session at any point if you feel uncomfortable.

When is the study over? Can I leave the study before it ends?

The study is expected to end in 2024, though your participation will end after your three-month long app testing period and completing all measures and meetings with the research team. The study may be stopped without your consent for the following reasons:

- The Principal Investigator feels it is best for your safety or the safety of the student. You will be informed of the reasons why.
- The Principal Investigator, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can stop the study anytime.

You may drop out of the study at any time. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will have no bearing on you/your student's services or relationship with the University of Pennsylvania or your student's preschool or school.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will not expire. Researchers continue to analyze data for many years, and it is not possible to know when they will be completely finished.

If you no longer wish to be in the research study, please contact the Principal Investigator, Heather Nuske, PhD, at (215) 746-6041. You can withdraw from the study by verbally stating that you do not wish to participate in the KeepCalm App Development Study. Clearly state your name and address and a written verification of your removal from the study will be sent to you within 30 calendar days. Alternatively, if you would prefer to provide written notification of withdrawal you may send this information to:

Dr. Heather Nuske

Penn Center for Mental Health
Department of Psychiatry
Perelman School of Medicine
3535 Market Street, Floor 3
Philadelphia
PA 19104

How will my personal information be protected during the study?

All information you provide will be kept confidential, except as required by law. Confidentiality will have to be broken if you express a current plan to harm yourself or others, or if you report that you have committed child abuse or neglect. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. The Institutional Review Board (IRB) at the University of Pennsylvania is responsible for protecting the rights and welfare of research volunteers like you. The IRB has access to study information. If information from this study is published or presented at scientific meetings, your name, your student's name, and other personal information will not be used. Confidentiality will be maintained through deidentifying any personal information obtained during the study, and only allowing access to such information to the research team. HIPAA guidelines will be followed (see more detail below).

What may happen to any identifiable information collected in this study?

In the KeepCalm app, the only identifiable health information of the child participation that will be entered will be their name or nickname entered by their teacher or parent and their heart rate data (as it will be linked with their name or nickname). The only identifiable information entered in the KeepCalm app for school personnel and parent participants will be your first and last name, email, and phone number.

As part of the study, you will complete demographic surveys and we will ask about the child's behaviors and any medications they are taking, as some medications are known to affect heart rate.

Following completion of the trial, all information you provide including information provided in the KeepCalm app will be de-identified. De-identified means that all identifiers have been removed. The information could be stored and shared for future research in this de-identified fashion. The information may be shared with other researchers within the University of Pennsylvania, or other research institutions, as well as pharmaceutical, device, or biotechnology companies. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again

seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Will I receive the results of research testing that may be relevant to my health?

As the KeepCalm app will continually monitoring heart rate in children during app testing, it is possible the data collected could help to screen for heart rate or cardiac abnormalities in the children that may need to be followed up with their healthcare provider. Parents who have signed the consent form will be contacted directly by Dr. Nuske and her team if the child has been found to have heart rate outside of the normal range for their age.

What happens if I am injured from being in the study?

If you are injured or feel emotional discomfort while participating in the study, you may contact the Principal Investigator or the emergency contact name on the first page of this form. They can go over procedures with you, share resources that may be available, and give you information on how to proceed. In case of injury resulting from this study, you will not lose any legal rights by signing this form. Also, you may contact your own doctor, counselor, or seek treatment outside of the University of Pennsylvania. Bring this document and tell your doctor/counselor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the numbers on the first page of this form for information.

If you are injured or feel emotional discomfort from being in the study, the appropriate care will be provided without cost to you through the University of Pennsylvania, but financial compensation is not otherwise available from the University of Pennsylvania. If you are injured or feel emotional discomfort while in the study but it is <u>not related</u> to the study, you and your insurance company will be responsible for the costs of that care.

Will I have to pay for anything?

There are no costs associated with participating in this study, beyond your time to complete the consent process, app-testing, interview, and survey.

The following section relates to your personal information and the health information of your child/student collected as part of the study

What personal information about me or my student may be collected, used, or shared with others?

In the KeepCalm app, children's heart rate will be monitored using a wearable heart rate tracker, in order to create an account in the app, we will ask your name, email, telephone number, and a nickname for your student. As part of your participation in the study through online surveys or in meetings, we will ask your name, address, telephone number, date of birth, Social Security Number, and personal and family medical history.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information is used to:

- conduct the research
- oversee the research
- ensure the research was done correctly
- to evaluate and manage research functions

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS, your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information will be stored in other HIPAA-compliant research databases and servers and data entered into the KeepCalm app will be stored in a custom-built server housed at Penn Medicine. With regards to security, the KeepCalm app uses Amazon Cognito, which requires multi factor authentication for all users. All data are encrypted in transit via HTTPS/SSL/TLS.

Who may use and share health information about me?

- The Principal Investigator of the study, Dr. Nuske, and the research team
- Other members of the student's educational team including their parent, teacher and aide (data recorded into the KeepCalm app only)
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my personal health information?

- Those working under the direction of the Principal Investigator for the study, Dr. Nuske, including the app development team
- The funding sponsor, the National Institutes of Mental Health (NIMH), and organizations supporting the sponsor

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

Once protected health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal information?

Your authorization for use of your personal information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the investigator for the study as described above. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my information?

Then you will not be able to be in this research study.

You will be given a copy of this Informed Consent Form and HIPAA Authorization Form describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns, or complaints regarding your participation in this research study, or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any questions, concerns, or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. If you have any questions or there is something you do not understand, please ask. You will receive a copy of this consent document.

By signing this form, you are indicating that you have had your questions answered and agree to take part in this research study. You are also agreeing to let the University of Pennsylvania use and share your information. If you don't agree to the data collection, use, and sharing of your information, you cannot participate in this study.

Fill out the following information to indicate your consent to participate in this study:

First name: _____

Last name: _____

Date: _____/ _____/ _____

Signature: _____

- ☐ I would like a summary of the overall findings of this research project
- ☐ I am interested in being contacted about other studies at the University of Pennsylvania