

Official Title: Utilizing a SMART Intervention Design to Optimize Participant Adherence in Home-based Behavioral Interventions

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Ame00154339

**UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY**

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Ame00151541 Study title: Utilizing a SMART intervention design to optimize participant adherence in home-based behavioral interventions

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Study Sponsor: MICHR - Pilot Grant program

You and your child are invited to take part in a research study. This form contains information that will help you and your child decide whether to join the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you and your child should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you and your child decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you and your child.

1.1 Key Information

Things you should know:

- The purpose of the study is to assess what type of supports should be offered to promote child adherence to a home exercise program.
- If you and your child choose to participate, your child will be asked to participate in a 3-month physical activity challenge (60-days). The goal is for your child to complete 3, 8-minute virtual instructor-led physical activity videos, online 5-days per week at home. These videos will be done in the comfort of your own home, and you will receive a 20-day calendar each month with links to the online daily



videos. The videos are not mandatory. We want to understand how many videos your child can do in a day.

- At the end of each month of the study, we will virtually check in with you and your child and see how many videos your child has been able to complete in a day.
- You may be eligible to receive additional resources to support your child in completing the daily physical activity videos in months two and three. In month two, these additional resources include daily pings to the parent cell phone or a personalized 20-day activity calendar with links to videos that match your child's preferred types of activities. In month three, you may again be eligible for either or both of these resources as well as family-based coaching. Throughout the three months, you may receive none of these resources, one, two, or even all three.
- Your child will be asked to wear a Fitbit physical activity watch while completing each physical activity video.
- You and your child will be asked to answer questionnaires at the beginning and end of the study as well as participant in an end-of-study interview.
- Questionnaires and interviews will be administered online. You and your child's data will be coded and stored securely, with access restricted to study staff. Electronic data will be protected according to University of Michigan standards.
- Risks or discomforts from this research include soreness after exercising, inconvenience of wearing the Fitbit, inconvenience/annoyance in receiving daily text messages, and potential discomfort during the family-based coaching session.
- The direct benefits of your participation are the opportunity for your child to complete 24 minutes (1/3 of the daily recommendations) of health enhancing physical activity.

Taking part in this research project is voluntary. You do not have to participate and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

2. PURPOSE OF THIS STUDY

Physical activity is one of the most effective ways to promote mental and physical health, prevent disease, and bolster a strong immune system. However, maintaining adherence to home exercise programs is a significant challenge, with adherence rates dropping to as low as 50%. This challenge is particularly problematic for programs aimed at improving mental health outcomes, such as at-home physical activity programs. There is a need to create effective physical activity programs that children are able to consistently participate in. This research will assess what supports will best help children participate in physical activity videos at home.

3. WHO CAN PARTICIPATE IN THE STUDY

3.1 Who can take part in this study?

A total of 30 children (ages 8-12 years old, male and female) and 1 parent/guardian per child will be recruited to participate in this study (N=60 parent-child dyads). Parent-child dyads will be recruited from various locations in Michigan. Healthy/normal weight as



well as those with overweight-, and obese-weight statuses will be recruited to participate in this study.

Inclusion Criteria- This study will include both males and females aged 8 to 12 years and their parent/guardian from various locations in Michigan. To be included in the study, children must:

1. Have access to a computer and internet at home.
2. Be proficient in English.

Exclusion Criteria- Children will not be eligible for the study if they meet any of the following conditions:

1. Currently taking medications (e.g., iron, metformin, chemotherapeutic agents) that could impact their ability to engage in physical activity.
2. Previously diagnosed with conditions that could impact their ability to engage in physical exercise (e.g., uncontrolled asthma).
3. Answering "YES" to any question on the Physical Activity Readiness Questionnaire (PAR-Q) indicating the participant has a heart condition, high BP, experienced chest pains or dizziness during daily activities, or require a doctor's recommendation for supervision during exercise.
4. Diagnosed with a physical or mental disability that would make it difficult to answer questions or follow directions without the help of an adult.
5. Parent or caregiver has a physical or mental disability that would make it difficult for them to answer questions or assist their child with project-related activities, such as completing questionnaires.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to my child in this study?

If you and your child agree to be a part of this study, you will be asked to complete the following, all online and at your own home:

- You and your child will be asked to complete a series of questionnaires online via a survey. Your child will be asked to answer questions about their enjoyment of physical activity and their typical physical activity participation. They will also be asked to answer questions about their emotion regulation and their anxiety and depression symptoms. You will be asked to complete a questionnaire asking about your child's emotion regulation and ways you support your child in being physically active. Questionnaires will be completed on a Zoom call with at least two research staff.
- The questionnaires that will be completed include the following:
 - **Physical Activity Enjoyment Scale.** This questionnaire will ask about how your child feels about exercise.
 - **Physical Activity Questionnaire for Children.** This questionnaire will ask about your child's habitual physical activity levels.

- **Patient Health Questionnaire (PHQ-9).** This questionnaire will measure depressive symptoms in your child.
 - **General Anxiety Disorder (GAD-7).** This questionnaire will measure worry and anxiety symptoms in your child.
 - **Difficulties in Emotion Regulation Scale- Short Form.** This questionnaire will ask about your child's emotion regulation, or their ability to manage emotions.
 - **Parental Support for Physical Activity Questionnaire.** This questionnaire will ask you about how you support your child's physical activity practices.
- How can I help my child's participation in the study?
 - You can help your child in all aspects of this study. If your child has difficulty answer the questionnaires, you can read the questionnaires to them and provide clarity to the questions. We do however ask, that you not answer the questionnaires for your child or unduly influence their responses to the questions.
 - You can aid in setting up videos, providing reminders to your children to complete exercises, log their activity, and wear their FitBit during exercise.
- All participants will be enrolled in an at-home exercise program, called Interrupting Prolonged sitting with ACTivity (InPACT) at Home. The videos that are part of the program can be accessed online. They incorporate cardiovascular exercises that get your heart rate up, strength-based exercises that help grow muscles, sports skills activities that are modeled based on popular sports, and mindfulness activities that promote calmness and relaxation. You can access these videos and view them on our website (inpactathome.umich.edu).
- For the first month of study, your child will be asked to participate in a 20-day physical activity challenge. The goal is for your child to complete three, 8-minute virtual, instructor-led physical activity videos, 5-days a week (30-45 minutes total per day). Again, the videos are not mandatory. We are trying to see how many your child can do in a day. The goal is 3 per day, but we are interested in seeing how many your child is able to do. You will receive a calendar with links to the online daily videos. At the end of each day, you will be asked to verify how many videos your child did on the calendar. At the end of the first month of the study, we will have a virtual check in and see how many videos your child completed each week.
- For the second month of the study, you will be asked to participate in a new 20-day physical activity challenge. The goal remains for your child to complete three, 8-minute virtual, instructor-led physical activity videos, 5-days a week. There are several potential variations in month two. You may be asked to continue with what you were doing in the first month and complete another 20-day physical activity challenge calendar with new videos, or you may be eligible to receive more resources in addition to the calendar to support your child in completing the



videos. If eligible to receive the additional resources, you will be randomized to receive one of two options. The first of these options involves receiving daily text messages to the parent phone. The second of these options involves your child receiving a different 20-day physical activity challenge calendar that has videos aligned with the activities your child most enjoys. At the end of the second month of the study, we will check in and see how many videos your child completed each week.

- For the third month of the study, you will again be asked to participate in a new 20-day physical activity challenge. The goal remains for your child to complete three, 8-minute virtual, instructor-led physical activity videos, 5-days a week. There are again several variations in month three. You may be asked to continue with what you were doing in month two (complete the physical activity calendar, complete the calendar and receive daily messages, complete the calendar personalized for your child). You may also be eligible for additional resources and again would be randomly assigned to the resources. These resources include: daily text messages to the parent phone, calendar personalized to your child's interests, or family-based coaching to address household barriers to the program. These resources may be offered in combination with each other. At the end of the third month of the study, we will check in and see how many videos your child completed each week.
- During all physical activity videos complete, your child will be asked to wear a small device that tracks their activity on their wrist (a Fitbit) and complete a one question assessment about their perceived exertion. Data will be monitored and downloaded by the research team.
- Following the completion of the study, you and your child will be asked to answer the same questions you did at the beginning of the study. You will also be asked to complete an interview here we ask you additional questions about your perceptions and experiences with the InPACT at Home program and the supports that you received over the three-month period.

Important information about the surveys:

For both you and your child, answering the surveys is voluntary. You do not have to answer any questions if you would rather not. You can skip any questions that you do not want to answer, whatever the reason, and you do not have to tell us why. It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

Important Information about your child's data

Your name and your child's name along with other information that can directly identify you and your child will be stored securely and separately from the research information we collected from you. Your child's and your research information (data) may be shared with other researchers, but any information that can identify either of you will be kept confidential and not be shared. We will keep the information we collect about you



and your child during the research for future research projects. Please see sections 5 & 8 for additional information about confidentiality.

4.2 How much of me and my child's time will be needed to take part in this study?

Questionnaires will take approximately 40 minutes total to complete before and after the study. Your child will be asked to complete three, 8-minute physical activity videos each day for 60-days (3, 20-day challenges). This should take approximately 30 minutes a day, 5-days a week for 12 weeks. As you support your child, we anticipate that you will spend approximately 15 minutes a day, 5-days a week for 12 weeks to participate in this study.

If eligible for the family-support based coaching, parents will receive 1 hour of coaching a week for four weeks with a trained, professional coach.

The end-of-study interview will take approximately 1 hour.

4.2.1 When will me and my child's participation in the study be over?

You and your child's participation in this study will be over after the 3-month physical activity challenge time period and return of the Fitbit to the study team.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will my child and I face by taking part in the study? What will the researchers do to protect us against these risks?

The researchers have taken steps to minimize the risks of this study. The known or expected risks are:

- *Physical activity videos:* During any type of exercise, there are slight health risks. However, in healthy children, they are small. Specifically, children may become tired during exercise or develop sore muscles, but this will be temporary. To mitigate these risks, we will communicate with the participants that these risks may occur due to participating in the exercise videos and suggest that they can perform stretches before and after the videos when needed.
- *Activity monitoring:* There is no risk of injury from the Fitbit to measure physical activity, though it may feel like a slight inconvenience wearing a wrist device during exercise. Because the device is plastic, there is little risk of an allergic reaction as compared to a metal device. If needed, the child participant can choose to wear the monitor over their clothes. It may be difficult to remember to put the wrist monitor for each exercise session, but this is very minor and is similar to taking a cell phone along for the day. Participants will not be held liable if the monitor is lost or broken. If the wrist monitor is lost in the mail we will send the participant a new one. However, if the participant misplaces it they will not be sent a new one.



- *Daily text messages:* There is a minor risk of psychological discomfort (annoyance) from parents who receive a daily text message ping reminder. Parents receive multiple text messages regarding their child's school activities and may become annoyed over time at receiving additional messages via text.
- *Coaching:* There is minimal risk for psychological discomfort. However, in the case of discomfort from participating in the interview you and your child may refuse to answer any questions and either of you can stop the interview process at any time. This measurement will be audio recorded to be able to review your responses. We will also suggest that you complete the interview in a private area and/or wear headphones to further protect your privacy.
- *Psychological and health behavior questionnaires and interviews:* These carry a minimal risk for emotional discomfort and stress. However, in the case of discomfort from completing the questionnaires or interview both you and your child can refuse to answer any questions and you can stop the interview process at any time. You and your child do not have to answer any questions you do not want to answer.
- *Confidentiality:* Because this study collects information about you, [one of the risks/the primary risk] of this research is a loss of confidentiality. See Section 8 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected, but we will tell participant's about any risks that come up and do everything to make sure they are safe and comfortable throughout the study.

The researchers will try to minimize these risks by providing participants with necessary resources and support when needed.

5.2 How could my child benefit if they take part in this study? How could others benefit?

Your child might benefit from being in the study. Your child will have the opportunity to complete 24 minutes of health enhancing physical activity 5-days per week in the home which will equate to meeting approximately 30% of the daily physical activity recommendations. A range of metabolic, behavioral, mental, and physical health benefits of regular physical activity have been documented in children. Your child also may not receive any personal benefits from being in this study, especially if there are many barriers to completing the videos. However, others may benefit from the knowledge gained from this study. Knowledge gained from this study can be used to inform the resources that need to be offered with home-based physical activity programs to improve child adherence so they can be used to promote physical activity at home for children.



5.3 Will the researchers tell me if they learn of new information that could change my child's or my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study.

6. ENDING THE STUDY

6.1 If my child or I want to stop participating in the study, what should I do?

You and your child are free to leave the study at any time. If you or your child leave the study before it is finished, there will be no penalty to you or your child. If you or your child decide to leave the study before it is finished, please tell one of the persons listed in Section 9. "Contact Information". If you choose to tell the researchers why you or your child are leaving the study, your reasons may be kept as part of the study record. The researchers will keep the information collected about you and your child for the research unless you ask us to delete it from our records. If the researchers have already used your information in a research analysis, it will not be possible to remove your information.

7. FINANCIAL INFORMATION

7.1 Will I or my child be paid or given anything for taking part in this study?

If your child completes one month of the study, they will receive a jump rope. If your child completes two months of the study, they will be compensated with a jump rope and a water bottle. If your child completes all three months of the study, they will receive a jump rope, water bottle and new FitBit valued up to \$75. Your child will be mailed the token gifts and new FitBit.

8. PROTECTING AND SHARING RESEARCH INFORMATION

8.1 How will the researchers protect my child's and my information?

We plan to publish the results of this study but will not include any information that would identify you or your family. It is very unlikely that anyone outside our team will gain access to you or your child's information or will discover that either of you participated in the research study because your name will not be attached to your data. All research data generated from the proposed work will be kept in locked files and on secure servers at UM by the principal investigator (Dr. Hasson), with access restricted to study staff. Specifically, your child will be assigned unique, coded, confidential identifiers (code numbers), which will be used to label all data forms and data entries. Identifiable information, such as name, will not appear on these materials. The key linking your child's identity to their unique code identifier will be kept in a confidential manner in a locked file cabinet in the Childhood Disparities Research Laboratory, with access only by the principal investigators and the research staff.

Your research information will be stored electronically on the cloud; the term "cloud" refers to large computers located in different parts of the world where individuals may keep and remotely access their personal and professional files. Each cloud service has its own policies and methods for preventing unauthorized individuals from accessing files stored on their cloud servers. The cloud service used to store files associated with this study meets University of Michigan protection standards. Additionally, any paper



copies of data will be kept in a locked cabinet in a locked suite with access only provided to the PI and study staff.

8.1.1. Special Protections

This research holds a Certificate of Confidentiality from the National Institutes of Health.

This means that we cannot release or use information, documents, or samples that may identify you in any action or suit except as described below. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings. An example of a situation in which the Certificate would apply would be a court subpoena for research records.

There are some important things that you need to know:

- The Certificate does not stop reporting or information-sharing that you agreed to in this consent document. For example, we may share information with appropriate authorities if we think you may harm yourself or others. We may also share your information with other researchers.
- The Certificate does not stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse and of some communicable diseases.
- The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.
- We may also release information about you to others when you say it is okay. For example, you may give us permission to release information to insurers, medical providers, or anyone else.
- The Certificate of Confidentiality does not stop you from personally releasing information about your involvement in this research if you wish.

More information about Certificates of Confidentiality and the protections they provide is available at <https://grants.nih.gov/policy/humansubjects/coc.htm>

If you tell us or we learn something that makes us believe that your child or others have been or may be abused or neglected, we may, and in some cases must, report that information to the appropriate agencies.

8.2 Who will have access to my child's and my research records?

There are reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- University, government officials, study sponsors or funders, auditors, and/or the Institutional Review Board (IRB) may need the information to make sure that the study is done in a safe and proper manner.
- University and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.



- If you tell us, or we learn something that makes us believe, that you, your child, or others have been, or may be, harmed, we will be required to report that information to the appropriate agencies. Included are situations of actual or suspected abuse or neglect, suicidality, or self-harm.

8.3 What will happen to the information collected in this study?

We will keep the information we collect about you during the study for future research projects, for study recordkeeping, or other purposes. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you. However, the information linking your data and your identifiers will be destroyed after 7 years.

The results of this study could be published in an article or presentation, but would not include any information that would let others know who you are without your permission.

8.4 Will our (my child and my) information be used for future research or shared with others?

We may use or share your research information for future research studies. If we share your information with other researchers it will be de-identified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies.

We will not store your research information or share it with other researchers.

8.4.1 Special Requirements. A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by the National Institutes of Health (NIH). This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

This trial will be registered and may report results on www.clinicaltrials.gov. This site will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

9. CONTACT INFORMATION

Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Rebecca E. Hasson Ph.D.

Email: hassonr@umich.edu



Phone: 734-763-8671

If you have questions about your rights as a research participant, or wish to obtain information, ask questions or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

University of Michigan
Health Sciences and Behavioral Sciences Institutional Review Board (IRB-
HSBS)
2800 Plymouth Road
Building 520, Room 2144
Ann Arbor, MI 48109-2800
Telephone: 734-936-0933 or toll free (866) 936-0933
Fax: 734-936-1852
E-mail: irbhsbs@umich.edu

You can also contact the University of Michigan Compliance Hotline at 1-866-990-0111.

10. YOUR CONSENT

Consent to Participate in the Research Study

By signing this document, you are agreeing to be in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records and I/we will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information in Section 9 provided above.

I understand what the study is about and my questions so far have been answered. I agree to take part in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Parent or Legally Authorized Representative Permission

By signing this document, you are agreeing to your child's participation in this study. Make sure you understand what the study is about before you sign. I/We will give you a copy of this document for your records. I/We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.



I understand what the study is about, and my questions so far have been answered. I agree for my child to take part in this study.

Print Participant Name

Print Parent/Legally Authorized Representative Name

Relationship to participant: • Parent • Spouse • Child • Sibling • Legal guardian • Other

Signature

Date

Consent to be Contacted for Participation in Future Research

Researchers may wish to keep your contact information to invite you to be in future research projects that may be similar to or completely different from this research project.

_____ Yes, I agree for the researchers to contact me for future research projects.

_____ No, I do not agree for the researchers to contact me for future research projects.