NCT06148246

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position:_____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the title of this research study (this "Research Study")?

Family Fit Iterative App Development IRB-01

3. Whom do you call if you have questions about this Research Study (the "Study Team")?

Danielle Jake-Schoffman, PhD; Principal Investigator
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Family Fit Research Team:
Email: familyfit@hhp.ufl.edu
Phone: (352) 294-1046

4. Who is paying for this Research Study?
The sponsor of this study is the National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development

5. In general, what do you need to know about this Research Study?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

a) In general, what is the purpose of the research? How long will you be involved?

The purpose of the research is to test whether the Family Fit app works well for families to support physical activity. You will use the Family Fit app and a Fitbit and app for the 12-week program period.

b) What is involved with your participation, and what are the procedures to be followed in the research?

You will be asked to participate in several assessments (5) over the next 12 weeks. If you choose to participate, we will complete the baseline assessment and fit both the parent and child with a physical activity monitor (called an accelerometer) to wear for the next seven (7) consecutive days to verify eligibility.

If you would still like to participate and are eligible, we ask that you come back to attend a trial kick off visit where both parent and child will be fitted with Fitbits. You, as the parent/guardian, and your child will use the Family Fit app to watch Skill Training Videos and set goals. We ask you to use your assigned Fitbit daily, and to synchronize each Fitbit every five (5) days. We encourage parents to engage in the Facebook Group.

At the end of 12 weeks, we ask you and your child to return to campus to complete a 12-week assessment, online survey, and 7-days physical activity monitoring (called accelerometry with an accelerometer). You will be provided stamped envelopes to return your accelerometers after 7 days of wear time. Finally, you will complete a brief audio-recorded interview providing program feedback. At the end of the study, you will be invited to attend a presentation about the study's results and conclusions.

c) What are the likely risks or discomforts to you?

There may be some discomfort from increasing physical activity levels. The possibilities include but are not limited to some muscle and joint stiffness. This stiffness generally subsides in 1 or 2 days and is not considered to be serious. As your fitness level increases and you become accustomed to the exercise, your energy levels should increase, and you should not experience muscle soreness.

If you agree to be interviewed as part of this study, your interview will be audio recorded. The audio recordings will be downloaded, saved on a password protected computer in our university office, and transcribed for responses to the questions. No names will be included on the typed files. If any personal information comes up during the interview, the information will be removed from the transcript. All audio recordings will be deleted from the network drive where it will be

stored, with assistance from the IT department once they have been de-identified and transcribed, at the conclusion of the study. Things you say during the interview may be used in future publications but will not be linked with your name or identifying information.

d) What are the likely benefits to you or to others from the research?

The proposed research will likely have direct benefit to you and your child. Using the Family Fit app and participating in the physical activity intervention and using a Fitbit may increase your physical activity leading to potentially decreased risk for cardiovascular disease and associated risk factors such as obesity and Type 2 diabetes. The research is also likely to have benefits to the greater community should results reveal a positive effect of the intervention. These benefits are substantial in comparison to the minimal risk possible.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

There are no alternatives to participation. Your participation is voluntary and does not affect or connect to your work, your child's school, or your healthcare.

Additional and more detailed information is provided within the remainder of this Informed Consent form. Please read before deciding if you wish to participate in this study.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this Research Study)?

The study is not connected to clinical care and has no impact on your ongoing healthcare.

7. What will be done only because you are in this Research Study?

You will be asked to participate in several assessments (5) over the next 12 weeks. If you choose to participate, we will complete the baseline assessment and fit both the parent and child with a physical activity monitor (called an accelerometer) to wear for the next seven (7) consecutive days to verify eligibility.

If you would still like to participate and are eligible, we ask that you come back to attend a trial kick off visit where both parent and child will be fitted with Fitbits. You, as the parent/guardian, and your child will use the Family Fit app to watch Skill Training Videos and set goals. We ask you to use your assigned Fitbit daily, and to synchronize each Fitbit every five (5) days. We encourage parents to engage in the Facebook Group.

At the end of 12 weeks, we ask you and your child to return to campus to complete a 12-week assessment, online survey, and 7-days physical activity monitoring (called accelerometry with an accelerometer). You will be provided stamped envelopes to return your accelerometers after 7 days of wear time. Finally, you will complete a brief audio-recorded interview providing program feedback. At

the end of the study, you will be invited to attend a presentation about the study's results and conclusions.

As part of your participation in the research, you will be video recorded, and audio recorded. Neither your name nor personal information will be identified on this picture or recording. Confidentiality will be strictly maintained. However, when the above is shown or heard, others may be able to identify you.

The above picture or recording will be destroyed once this research study has been completed.

Once this research study is completed, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

If you have any questions now or at any time during this Research Study, please contact one of the Research Team members listed in question 3 of this form.

8. How long will you be in this Research Study?

This study will take approximately 13 weeks to complete participation.

9. How many people are expected to take part in this Research Study?

We expect to enroll n=205 parent/child dyads for a total of n=410 individuals enrolled.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this Research Study?

One area of risk in this study is loss of privacy. There are two ways that privacy is at risk: (A) through data collected and stored by the study team at UF, and (B) by data collected and stored by third parties such as MEI and Fitbit. We cannot guarantee that data will not be unlawfully obtained.

Regarding data collected by our study team, we cannot guarantee that data will not be unlawfully obtained. To minimize risk of loss of confidentially, all data obtained directly by the study team will be held on a secure server accessed only by authorized study staff via password. Written materials will be stored in a locked location within Yon Hall at UF. Whenever possible, identifiers will be removed from study-related information. At the end of data collection, all identifying information will be removed from all data files. There is a minimal risk that security of any online data may be breached, but our survey host (REDCap) uses strong encryption and other data security methods to protect your information. Only the researchers will have access to your information on the Qualtrics and REDCap servers. No identifying information will be collected or connected with your responses, which will be anonymous. Data obtained during audio recorded interviews will not be linked with names or identifying information. The audiotapes will be downloaded from a digital recorder, saved on a password protected computer in our university office, and transcribed for responses to the questions. No names will be included on the typed files. If any personal information comes up during the interview, the information

will be removed from the transcript. Quotes from the interview may be used in future publications but will not be linked with names or identifying information. Audio recordings will be deleted after transcripts are made, no later than one year after the end of the study.

Data received and stored by Fitbit are not protected by the University and are subject to the terms outlined in the privacy policy of Fitbit. Any information you provide in the app or to the program may be stored by the app developer or its third parties. The data shared are not protected by the University and is subject to the terms outlined in the privacy policy of the app or program you are using. Information shared in the app is your decision and may identify you individually. If you decide to use the resources, you do not have to provide personal identifying information when you use them. If you use the resources, you are encouraged to use safeguards to protect your device, such as maintaining physical control of your device and password protecting your device.

Another potential area of risk is from increasing moderate-intensity physical activity, if you choose to do so, although this risk is no different than participating in other types of walking programs. Musculoskeletal aggravation is the most common adverse consequence associated with participation in physical activity. You are encouraged to speak with your primary care provider about increasing their your physical activity and to clear any new activities before beginning them for you and your child. Further, it is generally unsafe to use a smartphone or physical activity device (e.g., Fitbit) while distracted and could cause harm. Please do not use a smartphone or physical activity device while distracted to prevent injury or harm.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members or listed in question 3 of this form.

11a. What are the potential benefits to you for taking part in this Research Study?

The proposed research will likely have direct benefit to you and your child. Using the Family Fit app and participating in the physical activity intervention and using a Fitbit may increase your physical activity leading to potentially decreased risk for cardiovascular disease and associated risk factors such as obesity and Type 2 diabetes. The research is also likely to have benefits to the greater community should results reveal a positive effect of the intervention. These benefits are substantial in comparison to the minimal risk possible.

11b. How could others possibly benefit from this study?

Information collected from your participation will help expand knowledge regarding exercise promotion tools for families, which may benefit others.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

Participation in this study is voluntary. The alternative is to decline to participate. If you do not want to take part in this study, tell the person reviewing this consent or the Principal Investigators listed in Question 3 of this form, and do not sign this Informed Consent Form.

You may also refuse to authorize the use of your health information, but if you refuse, you will not be allowed to be in this research study. However, your decision not to sign this Authorization will not affect any other treatment you may be eligible to receive.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw, the Research Team may only use and disclose your information already collected for this research study. No additional health information about you will be collected or disclosed to the Research Team.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- You do not follow the instructions given to you by the study team.
- It is not safe for you to continue your study participation.

- Unforeseen administrative reasons.
- Further, it is generally unsafe for people who are pregnant to engage in weight loss efforts, and it is an exclusion criterion in our study. As such, you will be withdrawn from the study if we learn that you become pregnant. Please inform the study team if you learn that you are pregnant.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

The Investigator will pay for all services required as part of your participation in this study. There will be no cost to you.

15. Will you be paid for taking part in this study?

Upon completion of each qualifying study assessment, you and your child as a pair (or dyad) will be paid in the following amounts:

- Completion of the baseline online assessment and seven (7) days of accelerometry data: $20
- Completion of the 12-week online assessment, (7) days of accelerometry data and Fitbit syncing, Feedback Interview: $30

16. What if you are injured because of the study?

It is important that you promptly tell any member of the research team if you experience an injury or have questions about any discomforts that you experience while participating in this study. If you are injured, you will be treated or referred for treatment.

If you are injured as a result of being in this study, the costs of the diagnosis and/or treatment may be covered by the University of Florida or the study sponsor or billed to you or your insurer just like other medical costs, depending on a number of factors, such as if the injury was the result of the study intervention, or the way in which the study was conducted. The University of Florida and the study sponsor do not normally provide any other form of compensation for injury. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact the Principal Investigator listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your privacy and the confidentiality of your research records be protected?

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved

in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

NIH Certificate of Confidentiality:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

Consenting Adults. You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your privacy will be protected. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Adult Consenting for Self Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

_____ _____

Consent Signature of Parent/Legal Representative Date

_____ _____

Print: Name of Legal Representative Print: Relationship to Participant:

_____

Print: Name of Subject:

Minors (7-17yo) Who Cannot Consent But Can Read and/or Understand about this Research Study.
Although legally you cannot "consent" to be in this study, we need to know if you want to take part. If you decide to take part in this study, and your parent or the person legally responsible for you gives permission, that person will sign above, and you will sign below. Your signing below means that you agree to take part (assent). The signature of your parent/legal representative above means he or she gives permission (consent) for you to take part.

Even if your parent or legal guardian want you to be in this research study, you do not have to be involved and can say “No.” The study doctor or others involved in running this research study must describe all parts of this study with you, what medical tests might be require (examples might be blood test, pregnancy test, lung tests or other tests), what activities are involved, if any taking any medication is involved, and how long you will be involved with this research study. If you do not want to be involved in this research study, tell your parent or legal guardian and the study doctor and **do not** sign below.

_____ _____

Assent Signature of Participant Date