Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Digital Wellness Nurse – FIT Families: Virtual Family Intervention for Adolescent Obesity

Caregiver and Youth Informed Consent Document

TITLE: Digital Wellness Nurse – FIT Families: Virtual Family Intervention for Adolescent Obesity

PROTOCOL NO.: None
WCG IRB Protocol #20251040

SPONSOR: NIH NIMHD

INVESTIGATOR: Phillippe B. Cunningham, BA, MA, PhD
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United States

STUDY-RELATED-PHONE NUMBER(S): 843-876-1840 or 704-877-3478 (24 hours)

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

There is a possibility that identifiers might be removed from your private information or biospecimens and then used or distributed for future research studies without your additional informed consent.

RESEARCH CONSENT SUMMARY

You and your child are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. The purpose of this study is to test whether a mobile app, the Digital Wellness Nurse (DWN), can help African American families with weight problems lead healthier lifestyles. This is not a treatment study and your alternative is not to participate.

Participants in this study will receive education and tips on physical activity and healthy eating through weekly videos and online meetings with a community health worker (CHW) via the DWN app. The meetings with the CHW will take place once a week for 12 weeks. During these meetings, you and your child will set weekly goals and have the chance to earn incentives for meeting them. While in the study, you and your child will be asked to wear a Fitbit to track your physical activity and to complete a monthly survey about your eating and physical activity habits. At the end of the study, you will be asked to participate in a focus group and talk about your experiences with the app and the study. Sessions with the CHW and the focus group will be audio-recorded. The study will last for a total of 3 months and you and your child will receive study compensation for your time.

Participation in this study may improve you and your child's physical well-being, but that cannot be guaranteed. The greatest risks of this study include the possibility of injury if you increase your physical activity as part of this program and the loss of confidentiality.

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

DETAILED RESEARCH INFORMATION

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As study staff discusses this consent form with you and your child, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the research is to evaluate the DWN app to find out if it is helpful in delivering the FIT Families intervention. The study is sponsored by the National Institutes of Health (NIH). The investigator in charge of this study at MUSC is Dr. Phillippe Cunningham. Approximately 42 people will take part in this study.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. You and your child will be randomly placed into one of two groups by a computer. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. The two groups are: Digital Wellness Nurse-FIT (DWN-FIT) and DWN-FIT_Social Support (DWN-FIT_SS).
2. You and your child will be asked to download the DWN app onto your mobile phones and complete a few short surveys about your eating and physical activity habits.
3. You and your child will be given Fitbits to wear at all times during the study. You will also be given resistance workout bands, a yoga mat, and a body weight scale.
4. Over the next 12 weeks, you and your child will be asked to watch 3 to 5 videos each week and complete a few short surveys on the DWN app. The videos are no longer than 5 minutes each and will include physical activity and nutrition education and tips for healthy living.

5. You and your child will meet with a community health worker (CHW) once a week using the video chat feature on the app. The weekly sessions will last about 45 minutes to 1 hour. During the sessions, you and your child will talk about the videos you watched and set physical activity and nutrition goals for each week.
6. At the start of the study and then once a month for 3 months, you and your child will be asked to complete a short survey about your eating and physical activity habits.
7. At the end of the 3 months, you and your child will be asked to participate in a focus group. During the focus group, you will be asked questions about your personal experiences with the study and the DWN app. The focus group will be audio-recorded for research purposes.

You and your child will be asked to complete the tasks above no matter which group you and your child are randomly assigned to. The next section describes the two groups. Neither you nor the researchers pick which group you are in.

DWN-FIT Group:
Each week for 12 weeks, a set of 3 to 5 videos, each 5 minutes or less, will be available to you and your child on the DWN app. These instructional videos will cover topics such as physical activity, healthy eating, parenting strategies, and managing hunger and cravings. Once a week, you and your child will meet virtually with your assigned CHW through the app. The weekly sessions last about 45 minutes to 1 hour. During your sessions with the CHW, you and your child will talk about the videos and set weekly goals, such as step counts and completing food logs. You and your child will also fill out short questionnaires and track your daily input of fruits, vegetables, water and other foods in a food log on the app. Additionally, you and your child will be asked to weigh yourselves using the scale provided and record your body fat in the app.

You and your child will wear the Fitbits to track your daily steps, which the CHW can access in the DWN app. Some of the videos will show you physical activity workouts that you and your child will perform each week. These workouts will include a 5-minute warm-up, 20 minutes of high intensity interval training (cardio), 20 minutes of resistance band exercises, and a 5-minute cooldown with yoga stretches, all while wearing your Fitbit. The number of workouts you and your child will complete each week will be discussed and set during your sessions with the CHW.

The CHW will also be doing a reward system called Contingency Management, which uses incentives to encourage you and your child to meet your weekly goals: meeting a specified step count, filling out food logs, watching the videos, and completing the workouts. You and your child can earn $10 for each goal completed (up to $40 per week if all four goals are met). Additionally, you and your child will each receive $50 for attending each virtual session with the CHW. If you attend all 12 sessions, you can earn $600 each. You (parent) may also earn bonus incentives of $50 per month for reviewing your child's physical activity and food logs (you must review the logs each week for four weeks to qualify for the monthly bonus; a maximum of three bonuses can be earned). Your child can also earn bonus incentives of $50 per month if they lose at least one pound of weight per week over a four-week period (up to four bonuses in total).

DWN-FIT_Social Support (DWN-FIT_SS) Group:
Volunteers placed in the DWN-FIT_SS group will do the same things as those in DWN-FIT Group. In addition, if you are put in this group, you and your child will be asked to invite a family member or friend to be a supporter of your efforts in the study. This person will send you and your child encouraging text messages via the DWN app throughout the study. He/she will also join the focus group at the end of the study. The social support person will receive compensation ($60) each week for being a part of the study.

No matter which group you are placed in, your sessions with the CHW will be audio-recorded and any app chat messages sent between you and the CHW will be downloaded and kept for research purposes.

C. RISKS AND DISCOMFORTS

There are some risks associated with this study. One risk is possible injury due to increasing your physical activity. If you or your child experience injury due to increasing your physical activity, the researchers will refer you and/or your child to your healthcare provider. There is also a risk of loss of confidentiality regarding the personal information you provide as a part of participating in this study. All research information about you will be assigned an identification (ID) number and will be kept in locked file cabinets and all electronic research data will be stored on the secure password protected MUSC network.

D. CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

Information about your study participation will not be in your MUSC medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record. A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

E. COSTS

There will be no cost to you as a result of participation in this study. However, normal smartphone data usage and cell rates will apply while using the app. The study will not pay for any data charges associated with using the DWN app.

F. PAYMENT TO PARTICIPANTS

In return for your time and effort, you (parent) can receive up to $600 if you attend all 12 virtual sessions with the CHW ($50 per session x 12 weeks). You can also earn up to $480 if you meet all of the weekly goals over the 3 months ($10 per goal, up to 4 goals a week x 12 weeks). You may also earn bonus incentives of up to $150 for reviewing your child's physical activity and food logs (you must review the logs each week for 3 weeks to earn a $50 bonus for that month; a maximum 3 bonuses). You will be paid $195.55 for participating in the focus group. The total compensation if all tasks are completed is $1,425.55.

Your child can receive up to $600 for attending all 12 weekly sessions with the CHW ($50 per session x 12 weeks). Your child can receive up to $480 if all of the weekly goals are met during the 3 months ($10 per goal, up to 4 goals a week x 12 weeks). Your child may also earn bonus incentives of up to $150 if, over a 3-week period, he/she loses at least one pound of weight each week ($50 per bonus; a maximum 3 bonuses). Your child will be paid $195.55 for participating in the focus group. The total compensation if all tasks are completed is $1,425.55.

Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above. Details of the debit card system are explained on an additional sheet.

ClinCard is administered by an outside company called Greenphire. Greenphire will be given your name, address, SSN and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study that you are participating in. Bankcards can only be issued to an adult. If you are younger than 18 years, payments to you may be issued to your parent, in trust for you.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

G. ALTERNATIVES

Your alternative is to not participate in this study.

H. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you.

I. DISCLOSURE OF RESULTS

At the close of the study, if you would like to receive information about the study outcomes, please contact our staff, and we will be happy to share them with you. We do not share individual results with anyone.

J. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:
____Yes, I agree to be contacted.
____No, I do not agree to be contacted.

K. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that your child is injured as a result of participation in this study, you should immediately take your child to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that your child is in a research study. They will call your child's study doctor who will make arrangements for your child's treatment. If the study sponsor does not pay for your child's treatment, the Medical University Hospital and the physicians who render treatment to your child will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be billed for payment for all services rendered to your child.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

IRB APPROVED
AS MODIFIED
Jun 10, 2025

Volunteers Statement

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted.
- If assent is obtained, have the person obtaining assent document assent on the consent form.

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my child's participation in this study or study related injury, I may contact Dr. Phillippe Cunningham at 843-876-1840 or 704-877-3478 (24 hours). I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input about my child's rights as a research subject in this study, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

If you wish to participate, you should sign below.

_____ _____
Signature of Person Obtaining Consent/Assent Date *Printed Name of Minor Participant

_____
Signature of Adult Participant Date

*For Minors 12-17 years of age: "My participation has been explained to me, and all of my questions have been answered. I am willing to participate."

Signature: _____