NCT03168867

Effectiveness Trial of an E-Health Intervention To Support Diabetes Care in Minority Youth (3Ms)

Study Consent Form (Parental Permission)

Research Informed Consent/Parental Permission

Title of Study: Effectiveness Trial of an E-Health Intervention To Support Diabetes Care in Minority Youth

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Location(s): Children's Hospital of Michigan

Funding Source: National Institutes of Health

When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

Purpose

You are being asked to be in a research study of parenting interventions for families of teens with diabetes because your child has been diagnosed with type 1 diabetes for at least six months and is 10-15 years old. This study is being conducted at Children's Hospital of Michigan and Wayne State University. The estimated number of study participants to be enrolled at Children's Hospital and Wayne State University is about 125, with about 250 families enrolled nationally. **Please read this form and ask any questions you may have before agreeing to be in the study.**

The purpose of this study is to test a computer-based intervention that was developed for African American parents who have a teen with type 1 diabetes. The study will test if giving parents information during regular visits to the diabetes clinic about ways to parent their adolescent may help adolescents do better with their diabetes care.

Dr. Ondersma, who is a co-investigator on this research study, is President and Chief Science Officer of Interva, Inc. Dr. Ondersma is the inventor of the software that will be used in this protocol/grant. Wayne State University is the owner of this copyrighted software and Interva, Inc. licenses it from Wayne State University. Interva, Inc. will NOT bill this grant or Wayne State University for the use of this software. Wayne State University has attempted to minimize the potential Financial Conflict of Interest, but you, as the research participant, must make your own decision about participating in a research protocol in which Dr. Steven Ondersma has a financial interest.

Study Procedures

If you agree to take part in this research study, you will be assigned at random (like flipping a coin) to one of two groups.

Group 1: If you are assigned to this group, the computer will provide information about how daily diabetes care is related to blood sugar levels and what steps parents can take to be sure that their teen completes all their diabetes care each day. The computer will also ask about your impressions of the information that was provided, whether you want to try doing some of the recommended steps when you leave your clinic visit and ask you to develop specific goals for any changes you decide to make.

The computer intervention takes about 10-20 minutes to complete. Your child will continue to receive their regular diabetes care in the clinic.

Group 2: If you are assigned to this group, your child will receive regular diabetes care but no additional intervention.

In Group 1, you will receive the computer intervention at each of three diabetes clinic visits that you and your child attend in the next 12 months. How many intervention sessions you receive (1-3) will depend on how many times you come to diabetes clinic for appointments, as the intervention will only be offered to you when you and your child are seen for a regularly scheduled appointment.

If you enroll in the study, you and your child will also be asked to complete data collection four times. At each data collection visit, you and your child will independently complete questionnaires on a computer. The questionnaires will ask about your child's diabetes care, how you parent your child, family relationships, and your child's mood and adjustment. Your child's blood glucose meter will be downloaded to see the test results. Also, your child's hemoglobin A1c (HbA1c, a measure of how well their diabetes is controlled) will be measured with a fingerstick blood test (similar to testing their blood glucose level using their blood glucose meter). The first data collection visit will take place at the diabetes clinic at the time of a regular medical appointment. The next three data collection visits will take place in your home at a time convenient for you. Each study visit will last about 60-90 minutes.

If you participate in the study, we will also review your child's medical record for their diabetes medical history (e.g., date and type of diagnosis, current height, weight and pubertal status, what type of insulin is taken) and how often your child attended diabetes clinic visits.

You will be in the study for a total of about 12 months.

You may choose not to answer any of the questions and still remain in the study. Headphones will be provided so that your interactions with the computer will remain confidential. A research assistant will be present while you work with the computer to answer any questions you may have and help you with any problems using the computer.

Benefits

As a participant in this study, there may be no direct benefits to you; however, information from this study may benefit other people now or in the future. You or your child may also benefit from setting goals and making behavior changes that could improve his/her diabetes care.

Risks

By taking part in this study, you or your child could experience the following risks:

- Possible side effects from the fingerstick HbA1c, a blood sample, are pain, bleeding or infection at the blood drawing site and, rarely, nausea or a lightheaded feeling.
- You or your child may become tired from completing questionnaires and interviews. If you or your child become tired, you will be given a rest period or questionnaires can be read to your child. You or your child could also become upset from answering personal questions.

- Changing the way that you and your child interact around diabetes care could result in increased conflict between you and your child.
- Although every effort will be made to protect your study data by using secure websites to collect the information and storing your identity on password protected computers, it is possible that unauthorized persons could gain access to your personal information.

There may also be risks involved from taking part in this study that are not known to researchers at this time.

Alternatives
The only alternative is not to participate in the study. If you would like additional information regarding families, parenting or diabetes care, you may talk to the medical staff in the diabetes clinic and they can assist you or provide you with more resources.

Study Costs
You will not be charged for participation in the parenting program.

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered "standard of care" and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these "standard of care" charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

Compensation
For taking part in this research study, you will be paid for your time and inconvenience in the form of a ClinCard MasterCard gift card. You will receive $50 loaded to the ClinCard after the first study visit and $50 will be added to the card for each completed data collection visit 2, 3 and 4, for a total of $200. Wayne State University requires you to provide your social security number for registration of the gift card. You will not be paid for completing the computer program.

Research Related Injuries
In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. No reimbursement, compensation, or free medical care is offered by Wayne State University.

If a "research related injury" results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance.

A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.

It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights and are not freeing the sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study.

If you think that you have suffered a research related injury, contact the PI right away at 313-577-1055

Confidentiality

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. If photographs, videos, or audiotape recordings of you will be used for research or educational purposes, your identity will be protected or disguised.

A description of this clinical trial will be available on http://ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you are entitled to receive.

Questions

If you have any questions about this study now or in the future, you may contact Deborah Ellis, Ph.D. or one of her research team members at the following phone number 313-577-1055. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

_____	_____
Signature of participant / Legally authorized representative*	Date
_____	_____
Printed name of participant / Legally authorized representative *	Time
_____	_____
Signature of witness**	Date
_____	_____
Printed of witness**	Time
_____	_____
Signature of person obtaining consent	Date
_____	_____
Printed name of person obtaining consent	Time
_____	_____
Oral assent (children 7-12) obtained by	Date

*Remove LAR reference if you don't intend to consent participants that have or may have LAR.

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

_____	_____
Signature of translator	Date
_____	_____
Printed name of translator	Time

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HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and her research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and her research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place any time during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name (or initials), address (street address, city, state and zip code), elements of dates, telephone numbers, and medical record number.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: name (or initials), address (street address, city, state and zip code), elements of dates, telephone numbers, and medical record number.

Your study information may be used or shared with the following people or groups:

- The PI, co-investigators, and key personnel of WSU associated with the research project
- WSU's Institutional Review Boards (IRB)
- Authorized members of WSU's workforce who may need to access your information in the performance of their duties. [For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.]
- Other collaborating academic research institutions, which include: Lurie Children's Hospital, Chicago
- The study Sponsor or representative, including companies it hires to provide study related services, which include: National Institutes of Health
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

o During your participation in this study you will have access to your medical record and any study information that is part of that record. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the use and disclosure of your PHI for this research at any time, by writing to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization will not affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

_____ _____
Signature of participant Date

_____
Printed name of participant

- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

_____ _____
Signature of authorized representative Date

_____ _____
Printed name of authorized representative Relationship to the participant

_____ _____
Signature of person obtaining Authorization Date

_____ _____
Printed name of person obtaining Authorization Time