I Can Do This! Managing My Diabetes

NCT06695533

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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 25 people who are participating in this study.

Why is this study being done?

This study is being done to answer the question: Will a workbook of exercises help persons with diabetes better self-manage their condition? You are being asked to be in this research study because you are a person with diabetes.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in the study. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for a duration of 3 months. You will have two study visits in the clinic 12 weeks apart. At each study visit you will be asked to complete a survey. You will also be given a diabetes workbook to complete over the course of the 12 weeks. The workbook should not take more than about 15 minutes a day to work on. You will receive 2 check-in phone calls to complete over the phone surveys between the two study visits and reminder messages to complete the workbook.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. You may also benefit in improving your own knowledge about diabetes management.

What are the risks or discomforts you should know about before deciding?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

There is more information in the “Costs” section further below.

What Should You Do Next?

Read this form or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Take time to think about this decision to participate and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: I Can Do This! Managing My Diabetes: A Pilot Project using a Novel Word Game-based Workbook Intervention to allow People living with Diabetes to Increase their Diabetes Self-efficacy

IRB #: STUDY00008292

Principal Investigator: [redacted]

Funding Source:
1. Emory Academic Internal Medicine Center
2. Georgia Center for Diabetes Translation Research

Introduction

You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?

The purpose of this study is to help persons with diabetes self-manage their disease. You are being asked to be in this research study because you are a person with diabetes.

What will you be asked to do? If you qualify and choose to join the study, you will participate for a duration of 3 months. You will have two study visits in the clinic 12 weeks apart. At each study visit you will be asked to complete a survey. You will also be given a diabetes workbook to complete over the course of the 12 weeks. The workbook should not take more than about 15 minutes a day to work on. You will receive 2 check-in phone calls to complete over the phone surveys between the two study visits.

By participating in this study, you hereby agree not to reproduce, share, or sell any study materials, including but not limited to the study workbook, surveys, or any other research-related documents. Your signature on this form indicates your understanding that reproducing, sharing, or selling study materials could result in legal action or ending your participation in the study.

Who owns your study data?

If you join this study, you will be donating your data. You will not be paid if your data are used to make a new product. If you leave the study, the data already collected may still be used.

What are the possible risks and discomforts?

The most common risks and discomforts expected in this study are: that of lost time and possible disclosure of private information. All measures are taken to limit potential disclosure of information.

Will you benefit from the study?

You may have improved knowledge about how to self-manage your diabetes. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will get a $10 grocery gift card for each of 4 surveys completed and a $50 grocery gift card after submission of the workbook section and participation in a final interview for your time and effort for a total of $90 in gift cards upon completion of the study. Parking vouchers will be provided for your visits to the clinic. If you do not finish the study, we will compensate you for the visits you have completed.

Emory may be required to report your payment(s) to the IRS depending on how much you receive in a year. You must give the researchers a valid Social Security number or Taxpayer Identification Number for IRS reporting purposes. If you do not, your amount may be reduced because taxes are taken out. Please talk to your study team for more details.

You have the option of participating in this study without receiving any payment. If you chose to participate in this study without payment you will not receive any gift cards and you will not have to provide your Social Security number or Taxpayer Identification Number.

What are your other options?

If you choose not to join this study, you can get care outside of this study. You do not have to be in this study to be treated for your condition.

How will your private information be protected?

A study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases.
- Giving law officials information about abuse of a child, elderly person, or disabled person.
- Giving out information to prevent harm to you or others.
- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data you provide using a code. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

Confidentiality

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include the Office for Human Research Protections, the funders, the Emory Institutional Review Board, the Emory Office of Compliance. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

People Who will Use/Disclose Your Information:

The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study and give you study related treatment.
- Emory may use and disclose your information to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institutes of Health is the Sponsor of the study. The Sponsor may use and disclose your information to make sure the research is done correctly and to collect and

analyze the results of the research. The Sponsor may disclose your information to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes, a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact Dr. [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke**.

Consent

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form.

Your signature also indicates your agreement not to reproduce, share, or sell any study materials including the study workbook.

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Name of Subject

____ ____________________

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

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Signature of Person Conducting Informed Consent Discussion **Date** **Time**