Cognitive Behavioral Therapy for African Americans with Type-2 Diabetes

NCT03562767

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IRB00101847

You Are Being Asked to Be in a Research Study

This informed consent form is for Emory primary care patients African American Emory primary care patients who are participating in the ongoing research project titled "Cognitive Behavioral Therapy for African Americans with Type-2 Diabetes."

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 5-10 people who are being studied, at Emory University's primary care clinic located in Dunwoody, GA.

Why is this study being done?

This study is being done to answer the question: What are the perspectives, experiences and attitudes of African American individuals following Cognitive Behavioral Therapy intervention for type-2 diabetes health management?

- An exploration of changing perspectives of African American participants in regard to motivational therapy and cognitive therapy.

You are being asked to be in this research study because Diabetes is a disease that is known to affect your community.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for one group session. The researchers will ask you to do the following: Participate in one 30-minute group session with other study participants.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and type-2 diabetes in your community.

What are the risks or discomforts I should know about before making a decision?

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 – for this study, these include loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this discussion group is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance.

There is more information in the cost section below.

What Should I 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 (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title: Cognitive Behavioral Therapy for African Americans with Type-2 Diabetes

Principal Investigator: [redacted]
Assistant Professor, Department of Family and Preventive Medicine
Emory University, Atlanta GA 30322
Email: [redacted]

Funding Source: P30 GCDTR (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.

Study Overview

The purpose of this study is to explore your perspective on your recent participation in a Cognitive Behavioral Therapy intervention for type-2 diabetes management. The proper management and understanding of diabetes is an important way to improve the lives of people with the disease. The recent Cognitive Behavioral Therapy intervention you participated in with Emory's primary care clinic is important in understanding how to supplement medical care. We believe you can help us by providing us with your perspectives on the therapy and your management of diabetes. We want to lean what participants of the study have to say about how the intervention has changed their outlook on cognitive behavioral therapy and diabetes management. Your perspectives may provide insight on how to move forward with the research information and improve treatment efforts.

Procedures

We are asking you to help us learn more about Type-2 diabetes management using Cognitive Behavioral Therapy. We are inviting you to take part in this research project. If you accept, you will be asked to speak about your experiences with the intervention in a focus group with other study participants.

You will take part in a discussion with 5-10 other persons with similar experiences. This discussion will be guided by the focus group moderator, Ronald Cornely.

The group discussion will start with the moderator making sure that you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about Type-2 diabetes followed by questions

about the cognitive Behavioral Therapy intervention. We will give you time to share your knowledge. The questions will be about diabetes in your community, how is it viewed, and how the therapies of the study have informed your experiences with the disease.

We will also talk about community practices more generally because this will give us a chance to understand more about diabetes but in a different way.

We will not ask you to share personal beliefs, practices or stories and you do not have to share any knowledge that you are not comfortable sharing.

The discussion will take place in Emory's Dunwoody Primary Care Clinic, and no one else but the people who take part in the discussion and guide or myself will be present during this discussion. The entire discussion will be audio-recorded, but no one will be identified by name on the recording. The recording will be kept on password protected computer, which will only be accessible by study staff. The information recorded is confidential, and no one else except the study team will have access to the recordings. The recordings will be destroyed after they have been transcribed (within 4 weeks).

Risks and Discomforts

We are asking you to share with us some very personal and confidential information, and you may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the discussion if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview. Please be aware that there is no way to ensure that the other participants of the discussion will not divulge the content of the discussion.

Benefits

There will be no direct benefit to you, but your participation is likely to help us find out more about how to prevent and type-2 diabetes in your community.

Compensation

You will get $ 10 for the group discussion session. If you do not finish the discussion, you will still receive the compensation.

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 funder(s), 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.

Study records can be opened by court order. They may also be produced in response to a subpoena or a request for production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you, including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers,

researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

Withdrawal from the Study

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

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact one of the following study team members:

Principal Investigator:
[redacted]
Assistant Professor, Department of Family and Preventive Medicine
Emory University, Atlanta GA 30322
Email: [redacted]

Research Coordinator
[redacted]
MPH 2020, Rollins School of Public Health
Email: [redacted]

Graduate Research Assistant
[redacted]
[redacted] School of Public Health
Email: [redacted]

Contact Information

Contact [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

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

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

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