Program ACTIVE: Implementing a Cognitive Behavioral Therapy and Physical Activity Program for Black Men with Comorbid Diabetes and Depression

February 26, 2020

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Program ACTIVE: Implementing a Cognitive Behavioral Therapy and Physical Activity Program for Black Men with Comorbid Diabetes and Depression

Company or agency sponsoring the study:
National Institutes of Health, State of Michigan Health and Human Services
Michigan Center for Diabetes Translational Research

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Jaclynn Hawkins, PhD, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

Program ACTIVE (Adults Coming Together to Increase Vital Exercise) is an evidence-based, cognitive behavioral therapy (CBT) and community-based exercise intervention that aims to improve diabetes and depression outcomes that was developed for adults with Type 2 diabetes (T2D). Research suggests that Black men have more adverse life experiences than men of other racial/ethnic groups, and consequently, experience worsened mental health. Since CBT and exercise programs are the gold standard for treating comorbid T2D and depression, tailoring these existing interventions to meet the needs of Black men with T2D is critical, especially given that high rates of T2D and depression exist in

Black communities. Additionally, there is little researched about the barriers Black men with T2D experience when locating and using mental health care.

This research is studying whether changing an individual's behaviors may have an impact as a treatment or outcome for Type 2 diabetes and depression. This research will consist of randomizing participants into two groups: the intervention group receiving program ACTIVE for 12 weeks, and a group receiving care as usual from their established doctors or other medical care staff with no study-related changes to their lifestyle or nutrition habits.

This study involves a process called randomization. This means that the care you receive in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include feeling uncomfortable answering questions on a questionnaire, or feeling uncomfortable with finger pokes or other medical assessment tools. Other risks include feeling uncomfortable as a result of feeling no improvement of your current Type 2 diabetes diagnosis or depressive symptoms.

This study may not offer any benefit to you now but may benefit others in the future by establishing best practices for the delivery of services for African Americans with Type 2 diabetes and co-morbid depression by tailoring the pilot program to meet their cultural standards and expectations. A better understanding of how Black men respond to CBT and exercise programs will improve the precision and tailoring of self-management interventions. More information will be provided later in this document.

If you are in the intervention group, the first 14 weeks will be dedicated to exercise and talk therapy sessions. You can expect to participate in 150 minutes of aerobic exercise a week and 10 sessions of talk therapy during this time.

If you are in the control group, in the first 14 weeks you will continue with your usual routine as it relates to medical care, nutrition, exercise, and lifestyle. You will not be expected to make any changes to your routine diabetes treatment care and management or your diet or exercise regime.

Following the 14 weeks, there will be 3 post-assessment follow-ups at 15 weeks, 3-month, and 6-months. These post-assessments will occur only once at the noted times. We expect the amount of time you will participate in the study will be 6 months total.

You can decide not to be in this study. Alternatives to joining this study include joining a local gym or seeking Community Mental Health referrals.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Program ACTIVE (Adults Coming Together to Increase Vital Exercise) is an evidence-based, cognitive behavioral therapy (CBT) and community-based exercise (EXER) intervention that aims to improve diabetes and depression outcomes that was developed for adults with Type 2 diabetes. This research study is being conducted to learn what effects a regular exercise program of 14 weeks in combination with 10 talk therapy sessions has on diabetes self-management, glycemic control, and depressive symptoms in Black men with comorbid Type 2 diabetes and depression.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

By completing the prior screening with research staff, you met the eligibility criteria and are able to take part in the study.

3.2 How many people are expected to take part in this study?
40 subjects are expected to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
As a subject participating in this research study, you have certain responsibilities that apply to this study, like completing repeating surveys according to your ability, fulfilling weekly exercise times, and logging data for the research study at the Northwest Activities Center in Detroit, MI

If you consent to participate in this study, you can expect the following to occur:

1) If you consent to be part of the study, you will complete a health assessment. The assessment is comprised of 6 surveys and 3 health-related assessments (BMI using height and weight, blood pressure, and HbA1c reading)), and a glucose check. These assessments will be repeated at the 3-month and 6-month mark following the start of your time in the study. You will be given $20 for completing this assessment. If you **do not meet the eligibility criteria**, you cannot participate in the study.
2) Following the assessment, you will be randomized into either the intervention group or the control group, each composed of 20 participants.
    a) **If you are randomized into the intervention group, the following will occur during the first 14 weeks of the study:**
        i) For weeks 1 - 2, you will be introduced to the gym equipment. You will also take a 6-minute walk test to help you determine the level of intensity you can safely perform during exercise.

ii) For weeks 2 - 14, you will take part in 150 minutes of weekly aerobic exercise at the Northwest Activities Center in Detroit, MI. During this time, you will log your exercise using a log provided to you.

iii) For 10 weeks during this time period, you will also take part in 1 weekly session of in-person talk therapy with a clinician. This session may be audio recorded. The talk therapy is a requirement to take part in the study.

b) If you are randomized into the control group, the following will occur:

i) For weeks 1-14, you will continue your routine care as normal. You will not be expected to make any changes to your routine diabetes treatment care and management, or your diet or exercise regime. You will, however, be given a referral list to resources that may help you learn about or improve diet, nutrition, exercise, and mental health. Any lifestyle changes you learn from these resources may be included as you see fit into your routine schedule.

c) At the start of Week 15, all participants will participate in the following:

i) A post-treatment assessment consisting of 6 surveys and 3 health assessments (BMI using height and weight, blood pressure, and HbA1c). You will be given $20 for the full completion of this assessment.

ii) 3-month post-treatment assessment consisting of 6 surveys and 3 health assessments (BMI using height and weight, blood pressure, and HbA1c). You will be given $20 for the full completion of this assessment.

iii) 6-month post-treatment assessment battery consisting of 6 surveys and 3 health assessments (BMI using height and weight, blood pressure, and hbA1c). You will be given $20 for the full completion of this assessment.

If you are in the intervention group, you may also choose to participate in exit interviews to provide feedback on the intervention itself and make recommendations to the study team.

4.2 How much of my time will be needed to take part in this study?

If you are randomized into the intervention group, you can expect to participate in 150 minutes of weekly exercise for 12 weeks after the walk test and introduction to the gym equipment. The 150 minutes may be completed at your pace; a standard model is 30-minutes of aerobic exercise every week for 5 weeks. You can expect the 10, once-weekly in-person talk therapy sessions to take one hour. Each assessment that includes the 6 surveys and 3 health assessments will take approximately one hour.

If you are randomized into the control group, the assessment that includes the 6 surveys and 3 health assessments will take approximately one hour.

The study will last for 6 months and we ask that participants complete all 6 months, although there is no penalty for leaving the study at any time.

4.3 When will my participation in the study be over?

Your participation in this study will be over at the completion of the 6-month post-treatment assessment.

4.4 What will happen with my information and/or biospecimens used in this study?
Your biospecimens and collected information will only be shared within the research team for data analysis. To protect your privacy, your information will only be linked to an identifying number, not true identifying names, addresses, or phone numbers. Your biospecimen information includes glucose checks and HbA1c readings. Your collected information includes your demographic information and answers to all of your surveys during the assessment batteries. Following the completion of the data analysis, your information and biospecimens will be destroyed.

If the research study team develops a manuscript, your data may be shared on that manuscript and published. Your true, personal identifying information including your name, address, and phone number will not be shared on this manuscript. Only de-identified information will be shared.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:

1) There is a small risk of some discomfort during the finger prick at the assessment sessions, including when the HbA1c test is administered and when you check your blood sugar. There is also a small risk of dizziness and/or fainting from the finger prick procedure.
2) If you are randomized into the intervention group, you may feel uncomfortable during the talk therapy sessions.
3) If you are randomized into the intervention group, your blood sugar may rise or lower during your exercise routines.
4) An additional risk is related to the series of questionnaires. Some participants find that certain questions or information regarding diabetes self-management or gender roles makes them uncomfortable.
5) There is a possible risk of breach of confidentiality; however, the likelihood of this risk is small.

The researchers will try to minimize these risks by:

1) Only trained personnel will perform the finger prick to check your HbA1c level.
2) During the talk therapy, you can choose to not talk about a certain topic with the clinician or you may change the subject at any time.
3) Trained personnel will deliver glucagon to you if your blood sugar has dropped too low, you have more active insulin than you can adjust for, or you are unable to chew or swallow simple sugar.
4) You can choose not to answer any question for any reason. You will also have the opportunity to talk to the research staff about any subject that is uncomfortable to you.
5) We will inform all participants that anything related to the study or the participants of the study must be confidential.

As with any research study, there may be additional risks that are unknown or unexpected.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

If your blood sugar rises or lowers to the point of needed intervention during the exercise treatments or during the assessment batteries, you may take the time to inject insulin, take medication, or otherwise correct your blood sugar. If you require the use of a glucagon, trained personnel will administer it. If you are injured during the exercise intervention, first aid will be provided by trained personnel. If you experience any problems or side-effects as a result of your participation in the study, please contact Dr. Jaclynn Hawkins at 734-615-2817.

5.3 If I take part in this study, can I also participate in other studies?
Yes, you may take part in other research studies unless it is a study that affects your diabetes care. *Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies*. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. This study may establish best practices for the delivery of services for African Americans with Type 2 diabetes and co-morbid depression by tailoring the pilot program to meet their cultural standards and expectations. A better understanding of how Black men respond to talk therapy and exercise programs will improve the precision and tailoring of self-management interventions. This knowledge will establish a foundation of additional findings to support future studies.

We cannot promise that you, personally, will receive any benefits from being in the study. We hope that you will benefit from the interventions, should you be randomized into that group. Participants may also find it helpful to have the measurement results from the assessment sessions for both themselves and their doctor, including the HbA1c test. We hope that the findings of this study will be useful in improving care for all patients with diabetes in the future.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
Participation in this study is voluntary, so the alternative is to choose not to participate. Another alternative to joining this study is to join a local gym or seek services from Community Mental Health.

You may choose to attend exercise classes or seek out mental health treatment if you feel it is necessary.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No. If you were randomized into the intervention group, you may choose to complete an exit interview in which you will tell the research staff of your experience and any recommendations you have for improvement of the intervention.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs to you or your insurance company to participate in this study. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems

- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
All participants will take part in assessment batteries at (**1**) baseline, (**2**) post-treatment [week 15], (**3**) 3-month post-treatment, and (**4**) 6-month post treatment. At these times, you will be given $20 for completing each assessment, for a total of $80 if you remain in the study for the entire time.

If you are randomized into the intervention group, you will also be given a gym membership for 3 months at no cost to you. If you already have a gym membership, we will provide a 3-month gym gift-certificate for use at your convenience.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR DATA

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

This research will be covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that 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 provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child or older adult abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

9.1 How will the researchers protect my information?
We plan to publish the results of this study. To protect your privacy, we will not include any information that could directly identify you.

Audio recordings collected from assessments will be stored in the University of Michigan's secure server, MBox, and promptly deleted from audio recording devices. All identifiable data will be stored separately in a locked file cabinet in a locked office at the University of Michigan. Electronic data will be entered into encrypted data analysis platform and will be identified using subject numbers.

We will protect the confidentiality of your research records by using subject number to identify you. This information will be stored in a locked cabinet in a locked office at the University of Michigan. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project**.**

Data will be entered and uploaded onto University of Michigan secured servers using password protected computers. Only the Primary Investigator, Study Coordinator, and research assistants will be able to listen to the recording or read the typed version of the recording.

A description of this clinical trial will be available on http://www.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.

9.2 What data about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. This information includes:

- Questionnaires that you complete at each assessment session
- Health assessments that you complete at each assessment session

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration, and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my data?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has

been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my data expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Jaclynn Hawkins, MSW, PhD
Mailing Address: 1080 South University Avenue Ann Arbor, Michigan 48109
Telephone: 734-615-2817

Study Coordinator: Katherine Check, LMSW
Mailing Address: 1080 South University Ave., Ann Arbor, Michigan 48109
Telephone: 734-936-8646

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem.

This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

You will receive a copy of the signed and dated informed consent.

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-B

Consent audio recording solely for purposes of this research

This study involves video and/or audio recording and/or photography. If you do not agree to be recorded, you CAN STILL take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy):

_____