Techquity by FAITH!

NCT06187077

December 12, 2024

MAYO CLINIC

Name and Clinic Number

Approval Date: **December 12, 2024**
Not to be used after: **December 11, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Techquity by FAITH!: A Cluster Randomized Controlled Trial to Assess the Efficacy of a Community-informed, Cardiovascular Health Promotion Mobile Health Intervention with Digital Health Advocate Support

IRB#: 23-011118

Principal Investigator: LaPrincess Brewer, MD, MPH and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to develop a digital health equity toolkit for African American adults. You have been asked to take part in this research because you are an African-American adult in the Rochester or Minneapolis/St. Paul MN area faith communities.
What's Involved	Study participation involves participating in a series of 4, 2-hour, monthly virtual focus groups to learn about digital health equity and provide feedback on creation of a toolkit resource.
Key Information	You will be required to have a computer, tablet, or smartphone to connect to the virtual focus groups. You will be provided $50 per focus group you attend, with a total of up to $200. You will also receive a personal activity tracker (Fitbit) in appreciation of your time.

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Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive. ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. LaPrincess Brewer **Phone:** (507) 538-2517 **Study Team Contact:** Lainey Moen **Phone:** (507) 266-7062 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are an African-American adult within the Rochester, Minnesota or Minneapolis-St. Paul, Minnesota area faith communities.

About 20 people will take part in this part of the research study.

Why is this research study being done?

Unfortunately, African-Americans face health disparities which are often impacted by lack of knowledge or access to digital health tools. We hope to provide a resource that can offer education on digital and mobile health tools, such as using health care apps and wearables, accessing patient portals, common technology troubleshooting, and even issues of digital health equity and social justice. Our goal is to use this toolkit to train community members as "Digital Health Advocates" (DHAs) who can provide peer support to participants taking part in a future clinical trial using the FAITH! App. The FAITH! App was designed by members of the African-American faith community and the Principal Investigator and its goal is to improve heart health using the American Heart Association's Life's Essential 8. These are eight health behaviors and risk factors that keep your heart healthy.

The information from this study may lead to a health and wellness program and digital health literacy training program that can be run by African-American congregations throughout our nation to help prevent heart disease within the African American community.

Information you should know

Who is Funding the Study?

This study is being funded by the National Institutes of Health (NIH).

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Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You will be in this study for about four months.

What will happen to you while you are in this research study?

Before beginning any research activities, you will be asked to sign this informed consent form. If you agree to be in this study, you will complete an online questionnaire intended to assess your current knowledge of digital health concepts. We will also collect basic information about you (age, gender, etc.) in an online questionnaire.

You will participate in four monthly two-hour focus group discussions related to the development of our digital health toolkit. These meetings will take place virtually using a videoconferencing platform such as Zoom. We have developed a preliminary agenda for the focus groups as follows:

Meeting #1 – Overview and general feedback on digital tools/toolkit preferences
Meeting #2 – Initial review of toolkit prototype
Meeting #3 – Cultural tailoring
Meeting #4 – Final Review

These focus groups will be led by a trained moderator and will be audio-recorded and transcribed. Study team members from Mayo Clinic, along with collaborators from outside institutions, may be present at these focus groups. They will join in the discussion to answer questions, provide additional information and share their expertise in digital health equity and literacy.

However, none of your personal identifying information will need to be shared during these discussions. After the final focus group, you will complete a questionnaire to assess your satisfaction of the final toolkit.

What are the possible risks or discomforts from being in this research study?

Taking part in this research study may lead to added costs to you. As the focus groups take place online, there is a minimal risk that participants will incur costs related to their own personal smartphone/tablet data plan.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you do not follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You will learn about digital health technologies such as telehealth and patient portals, which can benefit you and members of your community. Others may benefit in the future from the toolkit developed with your feedback.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

There are no tests or procedures involved in this focus group series.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will receive $50 for each focus group you attend, for a total of up to $200 by virtual ClinCard. In order to provide this compensation, the study team may need your Social Security number.

You will be paid using the virtual Greenphire ClinCard, an electronic version of a debit card that your funds are loaded onto and can be used at your discretion. Your virtual card will be activated once registered to you, initiating an email to be sent, containing a link to access your virtual card online after the successful verification of your identity. When a visit is completed, the study team will load your study payments onto your virtual card. The funds will be available within 1 business day. For Mayo Clinic employees, research payments are included in your paycheck.

To get paid with the ClinCard, Greenphire will need to process certain personal information about you. Your name, address, and date of birth will be given to Greenphire ClinCard. This information will be collected from you by the study staff and given to Greenphire. If you choose to not provide the required information to Greenphire, the study team can have a check issued to you through the mail.

If you choose to participate, you will also be provided with a personal physical activity monitor (Fitbit) for participating.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name and address in order to issue a payment for your study participation. If you receive research payments totaling $600 or more in a calendar year, your Social Security number will be collected and a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Your information collected for this study will not be used or shared for future research studies.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. All participants involved will be assigned a study ID code to keep their identity private. If the results of the research are made public, information that identifies you will not be used.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature