Stroke Ready: A Stroke Preparedness Brief Intervention

NCT03831451

IRB Determined Exempt January 10, 2019

UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Brief Intervention to Increase Stroke Preparedness

Funded by: NIH/NIMHD

Principal Investigator: Lesli E. Skolarus, MD, MS

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All information in this form is important. Take time to carefully review this information. After you finish, 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 friends, family, or other doctors about your possible participation in this study. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

To determine whether our intervention helps people learn about stroke.

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?

Any adult over the age of 18.

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

Up to 200 subjects are expected to participate, subjects will be recruited throughout the Flint community.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

This study will take about 30 minutes. You will be randomized into a group that learns about stroke prevention or stroke preparedness. You will then be given a survey about your knowledge and attitudes about stroke. After completion, you will be randomly selected to receive a stroke prevention or a stroke preparedness brief intervention. The survey will then be repeated with some additional questions asked about whether you liked the brief intervention and materials. Finally, if you received the stroke prevention intervention, you will have the opportunity to receive the stroke preparedness intervention.

Your survey responses will be completely anonymous. No one, including members of our study team, will know which subjects gave which answers.

4.2 How much of my time will be needed to take part in this study?
The study is expected to take about 30 minutes

4.3 When will my participation in the study be over?
Your participation in the study will end today, after the last survey is completed.

4.4 What will happen with my information and/or biospecimens used in this study?
Collected information may be shared with NIH. Since this is an anonymous study, there is no way to link the study back to you.

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?

- It's possible that some of the questions may make you feel uncomfortable. If a question makes you uncomfortable, you can just skip it and go to the next question.

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

5.2 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. You should not take part in more than one study without approval from the researchers involved in each study.

5.3 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. We hope that this will improve stroke education.

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?
Participating in this research study is **voluntary**. You don't have to participate if you'd rather not.

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.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No.

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 do not follow instructions from the researchers.

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 or billing for this study.

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.

8.2 Will I be paid or given anything for taking part in this study?

You will receive $20 for completing this study.

8.3 Who could profit or financially benefit from the study results?

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 PROTECTED HEALTH INFORMATION

9.1 How will the researchers protect my information?

Your name or any other information that could identify you will not be collected. Your research information will be stored in a locked cabinet and will be inputted to a secure UMHS approved cloud storage, M-Box. There are no identifiers.

This research [is/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 NIH 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 [list what will be reported, such as child 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

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

9.4 When does my permission 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).

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: Lesli Skolarus, MD, MS
Mailing Address: 1500 E Medical Center Dr. Ann Arbor, MI 48109
Telephone: 734-936-9075
Study Coordinator: Casey Corches
Mailing Address: 1500 E Medical Center Dr. Ann Arbor, MI 48109
Telephone: 734-232-3799

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 (For International Studies, include the appropriate calling codes.)
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.