ID: UMCC 2021.076

Methods for Increasing Genetic Testing Uptake in Michigan

NCT05162846

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:
Methods for Increasing Genetic Testing Uptake in Michigan

Company or agency sponsoring the study:
National Cancer Institute funded grant, project number 1U01CA232827-01A1

Names, degrees, and affiliations of the principal investigator:
Elena Stoffel, MD, MPH, Internal Medicine – Gastroenterology, 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. In your decision to participate in this study, consider all of these matters carefully.

This research is studying whether a virtual genetics navigator or motivational interviewing phone calls help decrease barriers to clinical genetic testing when compared to usual care. This research will look at what the best way is to help people understand clinical cancer genetic testing and make the choice to get testing or not as appropriate for the person themselves. To do this, some participants will have access to an online tool to learn about cancer genetic testing, some will get phone calls from a genetic health coach, and some will continue their normal care with their primary care team. No genetic testing is being performed as part of this study.

This study involves a process called randomization. This means that genetic testing tools and resources you will interact with in the study is not chosen by you or the researcher. The study design divides study

participants into three separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures.

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 discomfort about topics discussed in the intervention. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by helping to answer questions about cancer genetic testing which might benefit you or your family. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 12 months.

You can decide not to be in this study. Alternatives to joining this study include talking to your primary care provider about cancer genetic testing.

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

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Between 5% and 10% of all cancers are caused by genetic changes that are hereditary, which means that they run in families. Some kinds of cancer or a family history of cancer means you are more likely to have a genetic change. Of those people with an increased chance to have a change, only about 30% of them get cancer genetic testing to find out if they do have a change.

This research study is looking at different ways to help people learn about cancer genetic testing and help them make the choice whether or not to get cancer genetic testing. This study is looking at two different educational interventions and their effect on healthcare compared to the usual care from their primary care team.

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?

To be able to take part of the study, you have completed the Family Health History Tool (FHHT) (HUM00180616).

You are also 18 years or older, able to speak and read English, and have a personal or family history of cancer that meets national guidelines for genetic testing. You also need to have reliable access to the internet using a phone, tablet, or computer.

If you already have an upcoming appointment scheduled with a genetics provider or have already had clinical cancer genetic testing, you cannot participate in this study.

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

855 subjects (285 in the control group, and 285 in each of the two intervention groups) are expected to participate over 4 years.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

After you consent to this study, the first thing you will be asked to do is create an online account on the MiGHT study website and complete a baseline survey. Once you have completed the survey, you will be randomized to one of three groups: control, virtual genetics navigator, or motivational interviewing phone calls. There is a 1-in-3 chance you will be randomized to any group.

The control group includes a website with resources about genetic testing and you are encouraged to speak to your primary care provider about genetic testing. You will receive an email and text message at 6 months after starting the study to complete a 6-month survey. You will also complete another survey 12 months after starting the study.

The virtual genetics navigator group is an interactive web-based tool you self-navigate through the website with information about genetic testing. You may access the virtual genetics navigator as many times as you wish during the six-month intervention period. At two and four months after you start the study, you will be asked to access the virtual genetic navigator and complete surveys. You will also complete another survey 12 months after starting the study.

The motivational interviewing will have up to 2 telephone coaching sessions (approximately 30 to 60-minutes each) with a genetics health coach. You will schedule a time to talk to a genetics health coach about genetic testing within the first month of starting the study. At the end of this first phone call, you will be scheduled for the second session which will be within 18 weeks of starting the study. After each coaching session, the genetics health coach that conducted the call will draft a short summary of the discussion and post the summary on your study portal. Your phone calls will be recorded on a secure study server for quality assurance purposes. This is required for the study. You will also be provided with resources for getting genetic testing from the website.

4.2 How much of my time will be needed to take part in this study?
Exactly how much time is needed will depend on which group you are randomized into.

- If you are randomized to the control group, you will be able to spend as much time as you would like on our website but there is no required amount of time.
- If you are randomized to the virtual genetics navigator group, you will be able to spend as much time as you like on our website during the 6 months. Most people will probably spend between 30 minutes and 2 hours on the website. Completing the surveys at 2 months and 4 months will take up to 30 minutes to complete.
- If you are randomized to motivational interviewing group, you will spend between 20 and 60 minutes on the phone with your Health Coach two times within 6 months.

For each group, a survey will be completed 12 months from the time you started the study. The survey link will be sent to you in an email.

4.3 When will my participation in the study be over?
You will be in this study for 12 months total. The first 6 months you will be actively participating in the study and will get your last survey 6 months later. Each survey will take between 20 and 30 minutes.

4.4 What will happen with my information used in this study?
With appropriate permissions, your collected information may be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

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?
You may become fatigued or inconvenienced by the time required to complete the intervention. It is possible that discussing/reading about personal and family history of cancer and genetic susceptibility

could provoke distress for some people. It is also possible that despite efforts to maintain confidentiality, a breach of confidentiality of health information could occur. To protect your privacy, all of your information is stored on secure servers at the University of Michigan. Your name is not stored in the same place as any other information. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

U-M study staff (including clinical genetic counselors) will be available to speak with subjects as needed and subjects will also be provided with the phone number for the MDHHS cancer genetics hotline

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

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
If you have problems as a result of this research, please reach out to the study team. The contact information is at the end of this consent.

5.3 If I take part in this study, can I also participate in other studies?
You may participate in other studies as long as they are not related to genetic testing.

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?
The largest benefit directly to you is a better understanding of clinical genetic testing. This could lead to a better understanding of the choice to get clinical cancer genetic testing or not.

Possible benefits of the research for society (or for future patients with this disease) include being able to better address the need for cancer genetic counseling and testing.

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?
There is no alternative to this study, but participation is completely voluntary. If you do not participate, you may choose to talk to your cancer treatment team about genetic testing or do nothing.

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". Your data collected up to the time you choose to leave the study will be used unless you request your information removed unless the data has already been de-identified in which case there is not be a way to identify your data and so the data may not be removed.

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

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.
- 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 participating in this study. 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?
You will receive $10 for completing the baseline survey, $15 for completing the 6 month survey, and $25 for completing the 12 month survey. You will receive each gift card within 2 months of completing each survey.

8.3 Who could profit or financially benefit from the study results?
No one will profit or financially benefit from the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

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.

9.1 How will the researchers protect my information?
To protect your information, it is stored on secure servers at the University of Michigan and your name is not stored in the same place as any other information. Because of this, it is unlikely that anyone other than the researchers could link any of this information to you.

This research is 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 National Cancer Institute 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.

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 protected health information (PHI) 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.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Demographic information
- Personal identifiers

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.
- University, Food and Drug Administration (FDA) 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
  - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- 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.

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 PHI?

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 PHI 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 will 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
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Dr. Elena Stoffel, MD, MPH
Mailing Address: 24 Frank Lloyd Wright Dr Ste 1300, Lobby C, Ann Arbor, MI 48105
[redacted]

Study Coordinator: Erika Amini
Mailing Address: 1500 E Medical Center Dr, Rm 3411, Ann Arbor, MI 48109
[redacted]

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.

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.)*

12. SIGNATURES

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 _____. 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): _____

Consent to 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 CANNOT 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): _____