Michigan Alcohol Improvement Network- Alcohol Reduction and Treatment Trial (MAIN-ART)

NCT04473482

IRB Approval Date: December 21, 2020

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Michigan Alcohol Improvement Network- Alcohol Reduction and Treatment (MAIN-ART) Trial

Company or agency sponsoring the study: University of Michigan and National Institute of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator:
Jessica Mellinger, MD MSc – Michigan Medicine Division of Gastroenterology and Hepatology

Study Coordinator:
Haila Asefa – Michigan Medicine Division of Gastroenterology and Hepatology

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 childcare, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research collects health-related information to better understand alcohol treatment engagement in patients with alcohol related liver disease. This research will compare a web-based alcohol reduction and treatment tool intervention to a group receiving usual care in patients with alcohol related liver disease. The intervention will use the Michigan Alcohol Improvement Network-Alcohol Reduction and Treatment Tool to correct potential misconceptions and to provide tailored preference sensitive alcohol treatment options. Your health-related information, as well as surveys about your health, and alcohol use will be collected for this research study.

This study involves a process called randomization. This means that whether or not you receive the web-based treatment tool 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 of stress or discomfort at having to answer survey questions about your health. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others through better understanding of the subject therefore better management of future patients with alcohol related liver disease. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 6 months.

You can decide not to be in this study and continue your usual care with your liver doctor.

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:

The purpose of the study is to see if providing patients with alcohol-related liver disease with tailored alcohol use treatment options will increase their engagement with treatment and correct possible misconceptions. This is an important area to study to help create ways to increase patients' knowledge about different treatment options as well as increase likelihood of seeking and participating in alcohol use disorder treatments.

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?

Anyone who meets the inclusion and exclusion criteria listed below may take part in the study.

Inclusion Criteria:

- Stated willingness to comply with all study procedures and availability for the duration of the study
- Age 18 years or older
- Enrolled at University of Michigan general hepatology clinics or inpatient wards at the University of Michigan Hospital System hospitals
- Documented diagnosis of alcohol-associated liver disease (ALD)
- Recent alcohol use of any amount within the past 6 months as assessed by either patient interview, medical chart review, or positive alcohol biomarker in the medical record.
- No alcohol use treatment within the past 1 month including, but not limited to:
    a. Professional mental health counselor led one-on-one therapy, group therapy, couples or family therapy with a primary aim of alcohol abstinence or reduction in alcohol use
    b. Community-based alcohol recovery groups (Alcoholics Anonymous, SMART Recovery, Celebrate Recovery, Refuge Recovery)
    c. Community-based church support groups primarily focused on alcohol abstinence or reduction in use
    d. Residential (inpatient) alcohol treatment
    e. Intensive outpatient programs
    f. Alcohol relapse prevention medications (disulfiram, acamprosate, naltrexone *or* prescriptions for non-FDA approved relapse prevention medications including gabapentin, topiramate, or baclofen when use of these medications is primarily for prevention of alcohol relapse)
- Access to a phone for purposes of follow-up
- Life expectancy greater than 1 month
- Ability to speak and comprehend English

Exclusion Criteria

- Unable to provide voluntary informed consent for any reason (including incompetency);

- Substantially cognitively impaired as evidenced by lack of orientation to person, place, or time or lack of ability to repeat back and answer screening questions
- Unable to read or understand English
- Active alcohol use treatment
- Undergoing active evaluation for liver transplantation, is listed for liver transplant, or is post-transplantation.
- Is enrolled in the multidisciplinary alcohol-related liver disease clinic at Michigan Medicine
- Any other medical condition or circumstance that precludes safe and meaningful participation in the study

3.2 How many people are expected to take part in this study?
Overall, 60 people are expected to be in the study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?
If you agree to take part in this study, you must read and sign this consent form or give verbal authorization (if recruited via phone) before any study related tests or procedures are performed.

You will be randomly assigned to group 1 or group 2 of the study. Random assignment is similar method to a coin flip, which means that you have and equal 50% chance of being assigned to either group 1 or group 2 of the study.

Group 1: You will be asked to complete few surveys about alcohol use and your overall health. After completing the surveys, you will be asked to complete the online behavioral tool. Once you have completed the online behavioral tool questionnaire, you will receive a printout of your results for alcohol use treatment preferences in addition to a pamphlet for referral to the University of Michigan Addiction Treatment Services. At 3 months and 6 months from today, you will again fill out few surveys about alcohol use and your overall health. Additionally, you will be asked to answer the first 10 questions from the online behavioral tool during your 6-month phone follow up.

Group 2: You will be asked to complete few surveys about alcohol use and your overall health. Once you have completed the surveys you will receive a pamphlet for referral to the University of Michigan Addiction Treatment Services. At 3 months and 6 months from today, you will again fill out few surveys about alcohol use and your overall health.

Table 1. Schedule of Events for Group 1

Study Timeline	Baseline visit (Today)	3-month phone call	6-month phone call
Eligibility Screening: We will ask you questions to make sure you are eligible to participate in the study.	X		
Informed consent	X	X	X
Demographics: Record age, gender, race, ethnicity and education	X	X	X
Medical history: Review your medical history, and alcohol use history	X	X	X

Surveys: questionnaires about your alcohol use and overall health	X	X	X
Michigan Alcohol Improvement Network-Alcohol Reduction and Treatment online tool	X		X*
Exit Interviews: open-ended researcher-delivered questions			X

* You will complete only the first module of the online behavioral tool during your 6-month phone follow up.

Table 2. Schedule of Events for Group 2

Study Timeline	Baseline visit (Today)	3-month phone call	6-month phone call
Eligibility Screening: We will ask you questions to make sure you are eligible to participate in the study.	X		
Informed consent	X	X	X
Demographics: Record age, gender, race, ethnicity and education	X	X	X
Medical history: Review your medical history, and alcohol use history	X	X	X
Surveys: questionnaires about your alcohol use and overall health	X	X	X
Exit Interviews: open-ended researcher-delivered questions			X

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

- Visit 1 (today) will take approximately 40 minutes if you are in group 1 and approximately 25 minutes if you are in group 2 (on top of your scheduled clinic visit if recruited in person).
- The 3-month follow up phone call will take approximately 20 minutes and the 6-month follow up phone call will take approximately 25 minutes if you are in group 1. If you are in group 2, the 3-month and 6-month follow up phone calls will each take approximately 20 minutes to complete.

4.3 When will my participation in the study be over?

The time needed to complete all study activities is 6 months. Your participation in the study will end when you have completed all study related activities, or when you decide to leave the study.

4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with the National Institute for Health.

With appropriate permissions, your collected information may also 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?

The known or expected risks are:

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.

The researchers will try to minimize these risks by:
If you need any clarification or have questions about the surveys our research staff will be ready to assist you as much as possible.

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.

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?
Due to the nature of survey based studies, the chances of injury are minimal. Please tell the researchers listed in Section 10 about any problems that you have during this study. You should also tell your regular doctors**.**

5.3 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. 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.

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?
This is not a treatment study. Participation in this study is completely voluntary.

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.

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 or billing for 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?
At the completion of the first visit you will receive a $30.00 gift card. Additionally, you will receive $30.00 for the first phone call follow up and $40.00 for the second phone follow up. As a result, you will receive monetary compensation of $100 total for completing the entire 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

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?
Keeping your information safe is very important to us. We have many safeguards in place to make sure that only people who need to see your information have access to it.

- Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.
- Instead of using your name, you will be assigned a unique code that will be on all of your research records.
- Any computer files that have your name on it will be password protected and only available to study staff that needs that information to do their job.

- All computer files are stored on secure UHMS servers behind firewalls. We never store any identifiable information on portable devices like laptops, thumb drives or tablets.
- All paper files will be filed in locked cabinets inside locked offices. Only people who need access to these papers will have the key.

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 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 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:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)

- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- 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.
- The researchers may need the information to check your test results or look for side effects.
- 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
    - Learn more about side effects
    - Analyze the results of the study
- 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 researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- 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 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: Jessica Mellinger MD, MSc
Mailing Address: 1500 East Medical Center Drive, Ann Arbor MI 48109
Telephone: +1 734-232-0284
Study Coordinator: Haila Asefa
Mailing Address: 1500 East Medical Center Drive, Ann Arbor MI 48109
Telephone: +1 734-232-0284

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 and may be entered into your regular University of Michigan medical record.)*

12. ORAL PHONE CONSENT AUTHORIZATION

Research Subject:

Name (Print legal name):_____

Date: _____

Patient ID:_____ Date of Birth:_____

13. IN-PERSON SIGNATURES

Sig-A

Consent/Assent 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-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): _____