Study title: Alcohol Screening and Preoperative Intervention Research (ASPIRE) Study

ClinicalTrials.gov ID: NCT03929562

IRB Study ID: HUM00156743

Informed Consent Document Approved: December 1, 2020

UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Alcohol Screening and Preoperative Intervention Research (ASPIRE) Study

Company or agency sponsoring the study: National Institute of Health

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Anne C. Fernandez, PhD, University of Michigan Department of Psychiatry
Study Coordinator: Lyndsay Chapman, MPH, University of Michigan Department of Psychiatry

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.

This research is studying whether changing an individual's behaviors may have an impact on the outcome of scheduled surgical procedures. This research will be a randomized pilot test of two conditions for reducing alcohol use prior to elective surgery. Participants will be assigned to either one brief advice session or two health coaching sessions and receive information about stress, alcohol use and surgical health before their procedure. Your health-related information will be collected for this research study through self-reported surveys, labs and medical chart review.

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 loss of confidentiality or feelings

of discomfort as a result of being asked personal questions. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future from the knowledge gained from this study. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be about 4 months. Your participation in the study will be over after you complete the 4-month follow-up survey.

Participation in the study is voluntary. If you choose not to participate, your treatment at Michigan Medicine will not be affected in any way.

If you choose 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:
Some previous research has shown that consuming alcohol prior to scheduled surgeries can increase the risk of post-surgical complications, such as infections, increasing the time it takes to heal or the time spent in the hospital. Importantly, stopping drinking prior to elective surgery can reduce these post-surgery risks in as little as four weeks. This study aims to learn more about how to improve patients' health before and after a scheduled surgery by seeing how effective two different conditions are at reducing alcohol use before and after surgery.

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?
Participants who take part in this study are 18 to 75 years of age, are scheduled for surgery at Michigan Medicine, and have reported recent alcohol use. Before you can participate in the health-coaching or brief advice program we need to make sure that your surgery is still scheduled. We also need to be sure that you have at least four weeks before your scheduled surgery so that we can complete the brief advice or health coaching sessions before your surgery.

Patients with different alcohol use experiences and histories are included in this study. It is important to give research staff complete and accurate information about your health behavior history so that we can make sure you are safe and that you are an appropriate candidate for this study.

3.2 How many people are expected to take part in this study?
Approximately 90 total subjects are expected to participate in this research study. 45 subjects will receive a brief advice session and 45 subjects will receive two health coaching sessions.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you decide to join the study you will complete a baseline survey online (or over the phone if you prefer). The survey will ask questions about your health, surgery, mood, stress, and alcohol/drug use. You will then be randomly assigned (like flipping a coin) to one of two study groups: either health coaching or brief advice.

Health-coaching: Participants assigned to the health coaching group will take part in two conversations with a health coach focused on health, stress, and alcohol use before surgery. You can participate through your choice of in-person meetings, over the phone, or using internet-based video calls (i.e. telehealth).

Brief Advice: Participants assigned to the brief advice group will take part in a single brief phone conversation about alcohol use from a trained member of our research team.

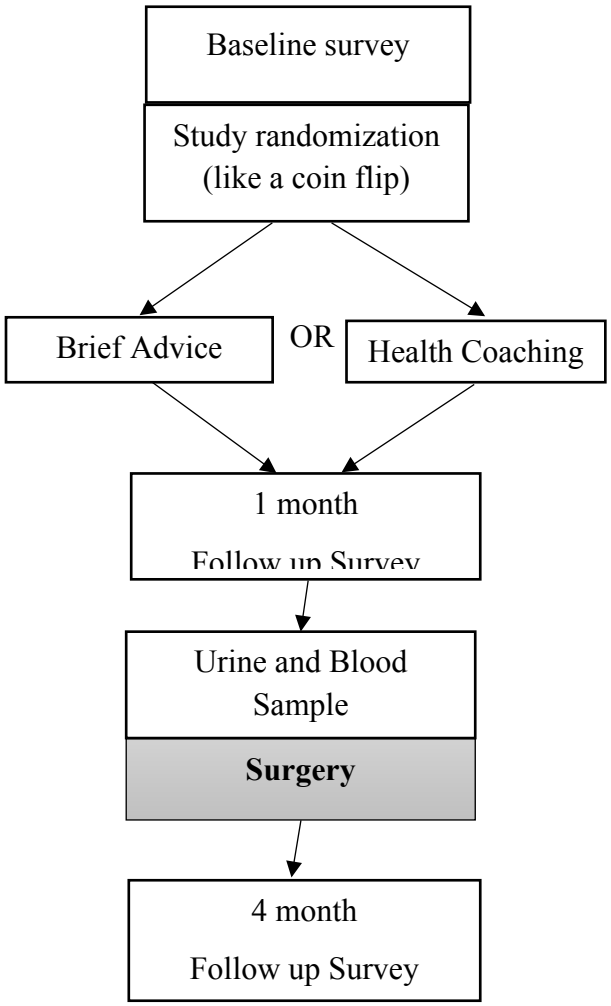
Regardless of which group you are assigned you will be asked follow-up questions about whether you found the information and participation useful, understandable, and important to your health. You will also receive written information about alcohol and surgical health by your choice of mail or e-mail. Health coaching and brief advice meetings are audio-recorded for quality monitoring and improvement.

You may receive study related information from a member of your clinical care team during one of your clinic visits.

For both groups on the day of surgery, a urine and blood sample will be collected and alcohol and drug screening labs ordered. This is for research purposes and results of these labs will not influence your candidacy for your scheduled surgery.

You will be asked to complete follow-up surveys online (or over the phone if you prefer) one month after study enrollment and four months after study enrollment. The surveys will ask the same types of questions as the baseline survey. When it's time for your follow-up survey, you'll receive an email or text invitation with a link and password to access the surveys. Finally, we will look at your medical chart 4 months after your surgery to assess surgical outcomes.

After the study is complete 20 participants that are randomly chosen will be asked to complete an exit interview about why they did or did not change their alcohol use, and what the role of the condition was in that decision making process. If you do not want to participate in the exit interview it will not affect your participation in the rest of the study.



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

The baseline survey will take approximately 45 minutes to complete, it will be done when you first speak or meet with the research staff around 5 weeks before your surgery.

The health-coaching session and follow-up questions will take approximately 60-75 minutes to complete and will occur during the month before your surgery, approximately 2 weeks apart. Thus, participating in both sessions will require 2 to 2.5 hours of your time.

The brief advice and follow-up questions will take approximately 30 minutes to complete and will take place over the phone.

The one month follow up survey will take approximately 40 minutes. The 4 month follow up survey will take approximately 45 minutes.

4.3 When will my participation in the study be over?

Each participant will be involved with the study in total for approximately 4 months. Your participation in the study will be over after you have completed the 4 month follow up survey or after you take part in the exit interview. The entire study is expected to last 2 and a half years.

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

Biospecimens will not be stored or shared outside of the study. Once the labs are completed your biospecimens will be disposed. Your biospecimen results and collected information may be shared with the National Institute of Health.

With appropriate permissions, your biospecimen results and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens 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 loss of confidentiality and feelings of discomfort as a result of being asked personal questions.

The researchers will try to minimize loss of confidentiality in the following ways. We shall put the information collected about you during the study into a research record. The information that you share will only be used for research purposes only. This research record will not show your name, but will have codes entered in it, that will allow the information to be linked to you. We shall treat your research record confidentially. We shall not allow anyone outside the authorized study staff to see your research record. You will not be identified in any reports on this study.

If you stop using alcohol or drugs abruptly you could be at risk of withdrawal. If your alcohol or drug use is significant enough that you are at risk of withdrawal you may be encouraged to taper alcohol or drug use prior to surgery rather than stopping abruptly. You will also be given referrals for substance use treatment and/or use of pharmacology when appropriate. If we are still concerned about your safety related to alcohol or drug withdrawal, we would inform your healthcare provider of this risk so that proper treatment can be offered to you.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

You may feel uncomfortable as a result of being asked very personal questions or may be upset about recommendations made during interviews. Our research staff will be trained to respond to your discomfort and can offer you referrals for services if necessary. You are free to terminate your participations at any time or refuse to respond to any survey item.

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?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems, even when the researchers are careful to avoid them. 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. You will receive information regarding alcohol use and health.

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. If you should choose not to participate, your treatment at Michigan Medicine will not be affected in any way.

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?

It is not anticipated that any harm would be experienced if you decide to 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 (e.g. your surgery is canceled).
- 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?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. 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.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). I f taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

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 get a MasterCard gift card after completing each study activity listed below. You must finish each survey to receive your gift card, but you can still skip any question you don't want to answer.

Study Activity	**Gift Card Amount**
Health Coaching	
Baseline survey	$30
First health coaching session and follow up questions	$40
Second health coaching session and follow up questions	$40
1-month survey	$50
4-month survey	$50
	Total: $210
Brief Advice	
Baseline survey	$30
Brief advice session and follow up questions	$30
1-month survey	$50
4-month survey	$50
	Total: $160
Qualitative exit interview (if selected)	$40

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

No person or organization has a financial interest in the outcome of the 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 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?

You may be worried about the privacy of your answers. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow

someone other than the researchers to link the information to you. All paper forms will be stored in locked file cabinets. Computer data file will be saved with passwords.

You have the choice to complete the interview over the phone or by video conference. If you choose to do a video conference we will use a encrypted, university-supported virtual meeting platform (e.g., BlueJeans, Zoom) for your interview with our study staff. Your confidentiality will be kept to the degree permitted by the technology being used. These platforms have a highly secure infrastructure that includes network and application firewalls, DOS protection, and penetration testing. It encrypts and transmits content via phone that supports HIPAA privacy rules.

We shall not allow anyone to see your research record including the clinical staff. However, we may inform clinical staff you are enrolled in the study so they can distribute study related information to you.

You will not be identified in any reports on this study.

There are some exceptions to confidentiality. If you report intent to do serious harm to others we are required to take steps to protect the person(s) endangered even if it requires telling the authorities without your permission. If you report intent to harm yourself, we would connect you with mental health professionals, and would only report this to outside agencies or authorities if we were still concerned for your safety. Your healthcare provider may be contacted by the study team if your alcohol or drug use is significant enough that you are at risk of withdrawal. If this were to occur, we would only share information about you that is relevant to your healthcare and safety. Reporting this information to your healthcare provider could affect your medical treatment.

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 or documents 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 or documents, 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 Institutes of Health which is funding this study. 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 intent to harm self or others, or child/elder abuse or neglect.

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.

9.2 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. In order to conduct this research study, researchers may use:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Alcohol/substance abuse treatment records
- Any records relating to your condition, the treatment you have received, and your response to the treatment
- 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
- 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 or presented at a scientific meeting, 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:	Anne C Fernandez, PhD
Mailing Address:	North Campus Research Complex, Building 16 2800 Plymouth Road Ann Arbor MI 48109-2800
Telephone:	734-232-0313

Study Coordinator: Lyndsay Chapman
Mailing Address: North Campus Research Complex, Building 16
2800 Plymouth Road
Ann Arbor, MI 48109-2800
Telephone: 734-232-0360
Email: lych@med.umich.edu

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.)*

12. 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-B

Consent/Assent to video/audio recording/photography 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 video/audio recorded/photographed.

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

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): _____