Alcohol Screening and Pre-Operative Intervention Research Study (ASPIRE)

NCT03929562

IRB Approval Date: May 7, 2021

Alcohol Screening and Pre-Operative Intervention Research Study

ASPIRE

National Clinical Trial Number: (*TBD)*

Principal Investigator:

Anne Fernandez, Ph.D., University of Michigan

Supported by:

National Institute of Alcohol Abuse and Alcoholism: K23 AA023869

Version Number: 1

12.14.18

TABLE OF CONTENTS

Page

PROTOCOL SUMMARY[CT.GOV]

Title:	*Alcohol Screening and Pre-operative Intervention Research (ASPIRE) study*
Study Description:	*The present study aims to conduct a randomized pilot test of two intervention conditions for risky alcohol use prior to elective surgery: Brief Advice and Health Coaching. This study builds on existing research indicating that moderate alcohol use (>2 drinks/day) prior to surgery increases the risk of postoperative morbidity, and heavy alcohol use (>4 drinks/day) increases the risk of postoperative mortality. This study will enhance our knowledge of how health coaching can influence problematic alcohol use, improve patient health, bolster hospital outcomes, and reduce the cost of postoperative care.*
Outcomes:	*The primary goal of this trial is to develop and examine the initial efficacy and acceptability of the health coaching intervention relative to brief advice with regards to reducing alcohol use prior to surgery. The primary outcome is change in alcohol use (average weekly drinking) and the secondary outcome is acceptability (perception of the interventions personal relevance). This trial has the following hypotheses but is likely under-powered to detect statistically significant differences.* *Hypothesis 1: Relative to the Brief Advice group, the Health Coaching group will experience greater reductions in average monthly alcohol use (quantity by frequency) based on the time line follow back.*
Intervention Information:	*The health coaching session will include two in-person individual sessions that will provide information about alcohol use reduction before and after surgery, delivered in a motivational interviewing format. Patients will have the choice of in-person or virtual meetings (via encrypted, university-supported virtual meeting platform). Brief advice will include a single 10-minute individual session of alcohol use reduction advice delivered virtually via encrypted, university-supported virtual meeting platform. The objective of both interventions is to motivate participants to maintain abstinence from alcohol for 4 weeks before and 6 weeks after surgery.*
Study Population:	*The study population will be approximately 90 elective or semi-elective surgical patients recruited from Michigan Medicine pre-operative clinics. Patients will be 18 to 75 years old and can identify as any gender or race/ethnicity.*
Locations:[eRsch]	*Patients will predominantly be recruited over the phone and online, after being identified by medical chart review. They may also be recruited in-person from outpatient Michigan Medicine clinics that evaluate patients for surgical candidacy at numerous locations*

	including, but not limited to, Taubman Clinic, Domino's Farms, West Ann Arbor, and Northville.
Estimated Study Start Date:	*March 1st, 2019.*
Study Duration:	*Two years and four months.*

1 BACKGROUND & RATIONALE

1.1 Background[eRsch]

Pre-operative alcohol use is one of the most common surgical risk factors and is one of the few that is modifiable[1]. A meta-analysis of 55 studies (combined N = 1,234,923) indicates pre-operative alcohol consumption (> 2 standard drinks/day) is associated with an increased risk of various postoperative complications including general morbidity, infections, wound complications, pulmonary complications, prolonged hospital stay, and admission to intensive care unit[2]. Heavier alcohol consumption (> 4 standard drinks/day) is associated with increased risk of postoperative mortality These risks are not specific to certain surgeries or subpopulations, they are evident across all surgeries[2] even after controlling for covariates such as gender and past year smoking status[3,4]. Importantly, short-term abstinence prior to elective surgery can reduce postoperative risks in as little as four to eight weeks (or less)[5]. Every additional point scored on the AUDIT-C increases the expected number of post-surgical complications by 29%[6] Pre-operative alcohol use is linked to longer hospital stays, admission to the intensive care unit (ICU), and increased probability of returning to the operating room[7]. All told, pre-operative risky drinking leads to numerous health consequences for individuals and increased costs to the healthcare system and society.

There is a scarcity of treatment and prevention research focused on pre-operative risky drinking. This is striking given the that the vast majority of hospital patients, including surgical inpatients, accept alcohol screening and BMI when it is offered[8–10]. Brief interventions are a recommended way to reduce risky drinking prior to surgery[5,6]; There remains a critical need for research to develop and evaluate the impact of pre-operative brief interventions on alcohol use and postsurgical outcomes. This study aims to take the initial steps to address this research gap.

1.2 Study Rational

There has been a call for additional research and development of behavioral interventions for alcohol use during the pre-operative period. However, these practice and research recommendations have not been implemented. At this time, there is a great need for research to identify and reduce alcohol use prior to elective surgery in order to improve patient health outcomes and reduce unnecessary healthcare utilization and costs. Therefore, this study will conduct a randomized pilot trial to evaluate initial efficacy of two interventions aimed at reducing alcohol use. Pre-operative patients (N = 90) will be recruited from University of Michigan Healthy System clinics and randomized to receive either a 2-session health coaching intervention (n = 45) or brief advice (n= 45).

2 OUTCOMES[CT.GOV;ERSCH]

2.1 Primary Outcome

The primary goal of this trial is to test initial efficacy of health coaching relative to brief advice. The primary outcome that this trial is powered to detect is change in alcohol use (defined as average weekly drinking) from baseline to one month follow-up (pre-operative outcome) and from baseline to the four month follow-up (post-operative outcome) in the Health Coaching condition relative to the brief advice condition.

2.2 Secondary Outcomes

The secondary outcome of this trial is acceptability of the two interventions. Acceptability is defined as the extent to which participant's perceive the intervention as personally relevant. We will consider the interventions acceptable based on post-intervention evaluations. Specifically, interventions will be considered 'acceptable' if the average acceptability rating reaches a threshold of 4 or more on a 5-point Likert scale.

2.3 Other Pre-Specified Outcomes

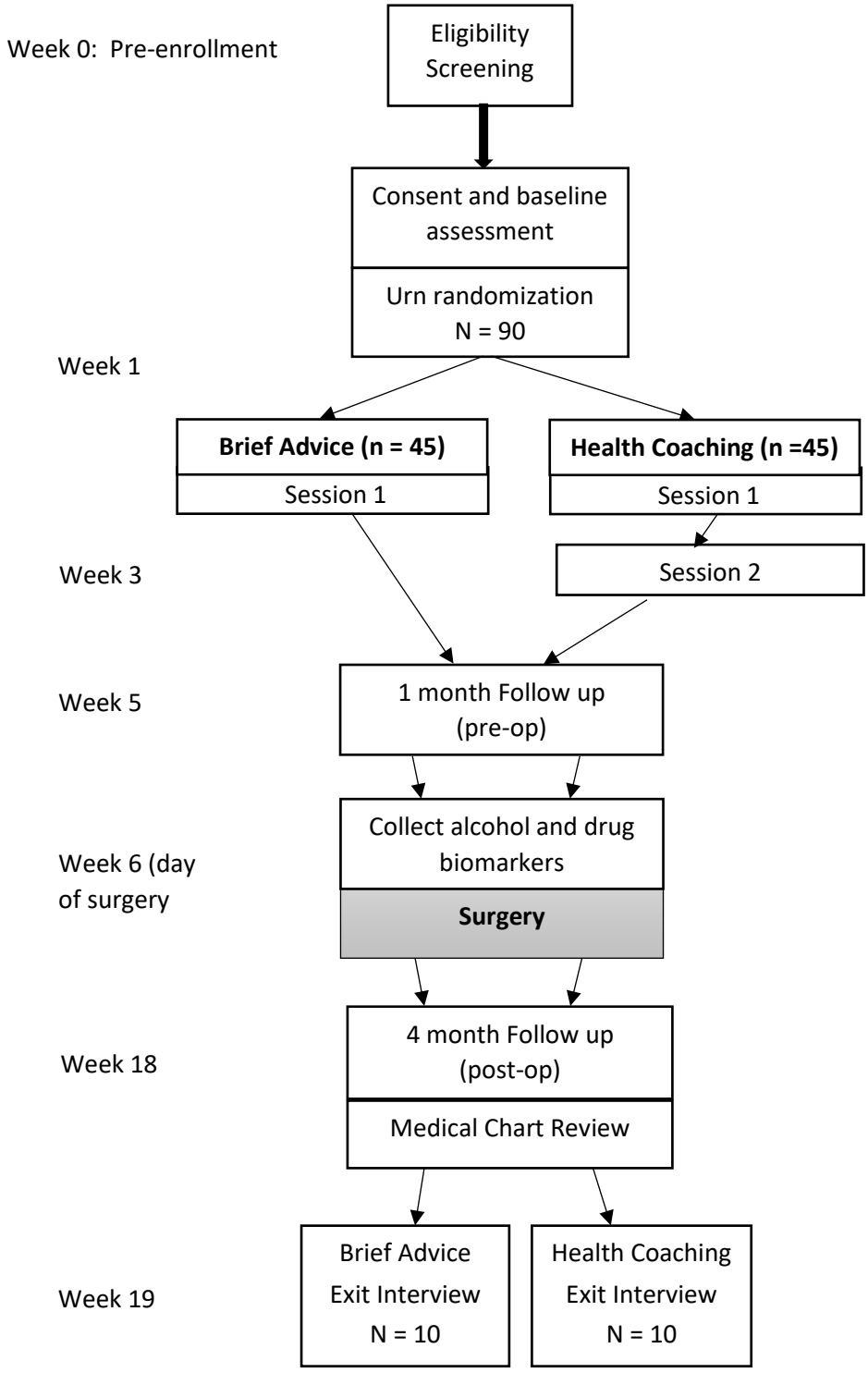
All other outcome measures will be exploratory.

3 STUDY DESIGN

3.1 Study Design

The study is a randomized clinical pilot trial that assesses preliminary intervention efficacy of a two session health coaching intervention relative to brief advice among pre-operative elective surgical patients and evaluates intervention feasibility, fidelity, appropriateness, and acceptability. Study subjects will be outpatients at the University of Michigan Health System and fulfill the study's inclusion criteria (see Section 4.1 below). Subjects will be randomized to one of two intervention conditions: Health Coaching or Brief Advice (See Section 5 below).

3.2 Study flow



4 SELECTION AND ENROLLMENT OF PARTICIPANTS

4.1 Inclusion Criteria[ct.gov;eRsch]

Patients will be eligible for participation if they are: 1) 18 - 75 years of age, 2) referred for elective or semi-elective surgery or pre-operative assessment in the next 120 days, and 3) Meet criteria for "risky drinking," scoring ≥ 5 on the first 3-items of Alcohol Use Disorders Identification Test (AUDIT). These cutoffs are associated with increased rates of postoperative complications among pre-operative patients following elective surgeries.

4.2 Exclusion Criteria[ct.gov;eRsch]

Exclusion Criteria.

Patient is…

1) unable to provide voluntary informed consent for any reason (including incompetency);

2) 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

3) Displays or shows evidence of psychotic symptoms

4) Unable to read or understand English

5) Undergoing surgeries that commonly require local anesthesia only (e.g. cataracts surgery, dental surgery, or other minor surgeries)

4.3 Recruitment[eRsch]

Given the different structure and patient flow at various pre-operative clinics within Michigan Medicine, participants (N = 90) will be recruited using several methods designed to minimize disruption to patient care. We will seek a waiver of informed consent to identify potentially eligible patients from the medical chart. This waiver will only apply to the initial medical pre-screen for eligibility criteria.

1. In-person recruitment: We will recruit patients in-person from the pre-operative and surgical clinics at Michigan Medicine. Research staff will be given tablets to consent to screening and to complete the screening through Qualtrics. Paper study screening questionnaires will be used as backup and may be distributed by research or clinic staff. The screening assessment will determine patient eligibility to participate in the Phase 3 randomized control trial. The participant will be assigned a random screen ID number. If the participant is eligible and is interested in participating, we conduct the consent process at that time. If this cannot be done right then, eligible subjects will be contacted by study research staff to schedule.

2. Phone recruitment: Patients who have appointments at Michigan Medicine surgical or pre-operative clinics will be identified through MiChart/medical record review. In clinics where we do not recruit in person, the clinics staff will provide patients with a letter at their clinic visit informing (see Phase 3 Patient Invitation Letter) them that they may be contacted by a member of the research team for study participation and give them the option to call the study to 'opt-out.' If the clinic cannot provide a letter, we will mail a letter to the patient at least 3 days prior to our recruitment contacts. We are seeking a waiver of consent for this initial medical record screen. Those patients who appear to meet study inclusion/exclusion criteria through MiChart medical review will be contacted by telephone for recruitment (see Study Screening Questionnaire) by study research assistants. They will also be contacted through text or e-mail (see text and e-mail recruitment scripts). The text and e-mail will simply inform them they may be eligible for a research study and include a link to the screening consent form and screening

questions. Those who are eligible will be asked to enter their contact information if they are interested in participating and the research assistant will reach out to them for consent and scheduling. Research assistants will make up to eight contact attempts by phone, text, and e-mail before indicating the patient was "unable to be reached." We will leave a maximum of three voicemails.

All patients approached either in-person or by phone will be tracked in an Excel spreadsheet. Identifiable information will only be retained for patients that enroll in the study. We will save only medical record numbers (MRNs) for all patients to ensure we do not attempt to recruit them more than once (e.g. if a patient has another surgery and enters into our recruitment list again MRN cross check will allow us to ensure we don't contact them again). Recruitment outcomes will also be tracked in the Excel spreadsheet to document eligibility, refusals and those the research assistant is unable to reach. Reasons for refusal or ineligibility will also be documented in the Excel spreadsheet.

4.4 Enrollment[eRsch;ct.gov]

When the screening survey is administered, the staff member administering the screen will obtain verbal consent (when recruitment by phone) or patients will be asked to agree to the consent on the tablet (if recruiting online). For phone screening the staff member will read aloud the verbal consent script, and obtain verbal consent from the participant before beginning the survey. The oral consent script will contain all information typically included in a written consent document including risk, benefits, and security procedures. Following screening, staff will document the outcome of the call, including: eligible, ineligible, refused, reason for refusal etc.

Participants who meet study eligibility criteria and have not met any of the exclusion criteria, will be given the option to participate in the study. Interested participants will either complete the consent form online or in-person and in all cases will be given the opportunity to ask questions prior to signing the consent. Eligible participants who complete the informed consent in-person will review it with the study research assistant and be given time to read the consent and ask any questions. Patients can also complete the informed consent online, which will contain all of the same information as the paper consent, before an intervention appointment. In all cases participants will be given the opportunity to ask questions before signing the consent. Reasons for refusal will be documented.

Completion of informed consent will be documented and tracked in REDCap. Informed consent documents will be stored in locked files as well as linked to the patient's data in REDCap. Each participant will be a given unique patient identifier in REDCap. Enrolled patients will be tracked in REDCap for surgery details, demographics, recruitment site, randomized intervention type, withdrawals, and intervention completion, and assessment completion.

At the time of the intervention, the research assistant will confirm that the patient is scheduled for surgery and the surgery date.

5 STUDY INTERVENTIONS[CT.GOV]

The ASPIRE study will offer two conditions that will occur before the patient's scheduled surgery. The conditions are (1) Health Coaching and (2) Brief Advice. Both interventions will be delivered by a trained member of the research team.

Brief Advice

The Brief Advice session will take place once at least four (4) weeks before the patient's surgery. The Brief Advice session will last approximately 10 minutes. Before the session, the patient will receive the study infographic that visually summarizes the effects of alcohol on surgical health, study recommendations of healthy behaviors, and alcohol use resources. During the session, the patient and trained research team member will refer to the study infographic and discuss alcohol use and health during the pre-operative period. If a participant cannot complete all study activities during one visit, we will allow participants to set an appointment to complete these activities within three days. A staff member at the pre-operative clinic will also give patient's an infographic about alcohol and surgical health during their clinic visit approximately two weeks prior to surgery.

Delivery**:** The Brief Advice session will be delivered by a trained member of the research team via telehealth or a telephone call, if the patient does not have access to a computer. In both cases, the research team will be using encrypted, university-supported virtual meeting platform with HIPAA-compliant conferencing services to contact the patient. Brief Advice sessions will be audio-recorded for quality assurance purposes. The infographic will be provided at the patient's pre-existing pre-operative clinical visit.

Health Coaching

Health Coaching will consist of two (2) sessions beginning four (4) weeks before the patient's surgery. The sessions will be spaced two (2) weeks apart to accommodate patient response to the intervention. Each Health Coaching session will last approximately 50 minutes. During the Health Coaching sessions, a trained research team member will discuss alcohol use and health during the pre-operative period by using motivational enhancement therapy techniques to improve the patient's motivation to change. Additionally, the research team will provide the patient with alcohol use resources during the Health Coaching sessions. If a participant cannot complete all study activities during one visit, we will allow participants to set an appointment to complete these activities within three days. Follow-up surveys will take place at one-week prior to surgery and one-month post-surgery. A staff member at the pre-operative clinic will also give patient's an infographic about alcohol and surgical health during their clinic visit approximately two weeks prior to surgery.

Delivery: All Health Coaching sessions will be delivered by a member of the research team trained in motivational interviewing. The research team will give patients the option of in-person meetings, or virtual meetings via encrypted, university-supported virtual meeting platform . The Health Coaching sessions will be audio-recorded for quality assurance purposes encrypted, university-supported virtual meeting platform with HIPAA-compliant conferencing services will be used for the videoconferencing or phone meetings. In-person meetings will take place at UM or a building within the UMHS, or a mutually agreed upon location within the community. The infographic will be provided at the patient's pre-existing pre-operative clinical visit.

Intervention Targets (mechanistic and clinical outcomes):

The goal of the pilot trial is to assess the initial efficacy of health coaching relative to brief advice and determine the acceptability and feasibility of both interventions. This study is underpowered to assess mechanisms of change.

Supportive Theories

Supportive theories include social learning theory and motivational interviewing

5.1 Handling of Study Interventions

N/A

5.2 Concomitant Treatment

We will not exclude participants enrolled in other studies and/or health programs.

5.3.1 Allowed Interventions – N/A

5.3.2 Prohibited Interventions – N/A

5.3 Lifestyle Considerations

None.

5.4 Intervention Discontinuation

Withdrawal of consent will result in true study discontinuation with no interview or assessment performed. Any information collected before withdrawal will be kept as part of the subject's record. The study will document the patient's reason for withdrawal, if available, to track for study purposes.

Patients can also be withdrawn by the study if they become ineligible after consent. These reasons include (1) surgery cancelation or rescheduling with a greater than 6-month delay, (2) demonstrating substantial cognitive impairment at two time points as evidenced by lack of orientation to person, place, or time or lack of ability to repeat back and answer questions; or (3) displays or shows evidence of psychotic symptoms, (4) fails to follow instructions of the researchers.

5.5 Treatment Fidelity

Fidelity to session content will be evaluated after each study session using a content checklist designed to ensure central elements of the health coaching and brief advice sessions are delivered. Motivational interviewing competence and adherence will be evaluated using the Motivational Interviewing Treatment Integrity (MITI) measure. All health coaching and brief advice sessions will be audio-taped, coded using the MITI, and evaluated using the fidelity checklist to ensure they adhere to protocol. Bi-weekly supervision will take place to provide fidelity feedback to interventionists and ensure quality and consistency of intervention delivery.

5.5.1 Overall compliance

A participant will have completed the brief advice intervention after receiving the 10-minute brief advice session. A participant will complete health coaching after receiving

the two 50-minute health coaching sessions. We will track intervention completion in REDCap.

5.5.2 Treatment Design

The treatment is designed to provide health education, psychoeducation and increase motivation to change using a motivational interviewing framework.

5.5.3 Interventionist or Provider Training

All staff delivering sessions will take part in a two-day motivational interviewing training and weekly meetings with the study PI (a licensed clinical psychologist) to learn both specific intervention content, and MI delivery. They will also listen to audio-recordings of completed sessions from the refinement trial. After training, interventionists will need to complete at least three practice sessions. One of these sessions must be audio-recorded and coded with the MITI and our fidelity checklist and meet an 80% competency to MI, as well as deliver 90% of elements from the content checklist.

5.5.4 Delivery of Treatment

See above

5.5.5 Receipt of Treatment

See above

5.5.6 Enactment of Treatment

See above

6 STUDY PROCEDURES[ERSCH]

For Phase 3 we will conduct a randomized pilot trial test of Health Coaching and Brief Advice interventions to reduce alcohol use prior to elective surgery. The goal of the pilot trial is to assess the initial efficacy of Health Coaching relative to the Brief Advice Intervention and determine initial acceptability, feasibility, and fidelity of both conditions. Participants have a choice of intervention modality and they will either take place in-person or as a virtual meeting using an encrypted, university-supported virtual meeting platform. The in-person meetings will take place at either the Rachel Upjohn Building, in MCRU research space, or at a building within UM or UMHS, or a mutually agreed upon location within the community. If a participant cannot complete all study activities during one visit or virtual visit, we will allow participants to set an appointment to complete these activities within three days. This study has one baseline assessment. Follow-up surveys will take place at one-month post-baseline (Follow up 1; one week pre-surgery) and at four-months post-baseline (Follow-up 2; 3-months post-surgery).

Randomization

Participants will be urn randomized to study condition using computerized random number generator. Groups will be balanced based on gender.

Assessment and Measures

Baseline assessment will take place at least four weeks prior to surgery. The baseline assessment will take approximately 40 minutes to complete. Thus, the first appointment will take up to 120 minutes for those randomized to health coaching (15 minutes to

review the consent form; 40 minutes for baseline assessment; 50 minutes for the intervention; 10 minutes for the post-intervention feedback; and 5 minutes to provide the incentive) or 75 minutes for those assigned to receive brief advice (15 minutes to review the consent form; 40 minutes for baseline assessment; and 10 minutes for the brief advice intervention and 10 minutes for intervention feedback evaluation).

All baseline and follow-up assessments will be designed and administered using the Qualtrics Research Suite (http://www.qualtrics.com). The project-specific Qualtrics site is protected with a researcher-designated login name and password. The site houses the surveys and compiles data that staff will then transfer to a password protected Access database on the Department of Psychiatry secure network. For the web-based follow-up surveys, participants receive an email invitation inviting them to take the survey on-line and directing them to the Qualtrics site. An additional password may be given to participants in order for them to access to the site. There are systems in place that prevent the survey from being taken by the same user more than once. No identifying information is linked to the participants. There are security precautions in place to protect against unauthorized access, but there is a small risk of unauthorized access. Information regarding Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

Baseline and Follow-up assessment. Baseline and Follow-up assessments will be completed by participants online (via tablet or home computer) at baseline, at 1-month follow-up (approximately one-week pre-surgery), and at 4-months follow-up (approximately three months' post-surgery). The schedule of assessments is indicated in the Schedule of Study Activities. Participants will be notified by e-mail or text message when they are scheduled to complete follow-up. If participants do not have internet access or do not want to complete the baseline or follow-up assessment online, research staff will conduct the follow-up assessment over the telephone, reading the questions from Qualtrics.

Self-Report Measures

Alcohol use assessments administered at baseline and follow-up include the Alcohol Use Disorders Identification Test (AUDIT)[11], the Alcohol Timeline Followback (TLFB)[12], the Severity of Alcohol Dependence Questionnaire (SADQ-C)[13]. The primary outcome (average weekly drinking using the TLFB) is gathered here. All other self-report measures are exploratory.

Measures of alcohol use problems, behaviors, and cognitions include the Short Inventory of Problems (SIP)[14], the Penn Alcohol Craving Scale (PACS)[15], the Readiness-to-Change Ruler[16], Situational Confidence Questionnaire (SCQ)[17].

Drug use assessments include the NIDA modified Alcohol, Smoking, and Substance Involvement Screening Test (ASSIST)[18] and the Current Opioid Misuse Measure (COMM-8)[19]. Health and functioning assessments include Patient-Reported Outcomes Measurement Information System (PROMIS-29)[20].

Other measures related to treatment mediators and moderators include assessments of Social Support[21,22], Health Service Utilization[23,24], Pre-operative Surgical Anxiety[25], knowledge of surgical risk factors, pain management practices, and healthcare surgical

risk assessment.

Alcohol and Drug Use biomarkers. On the day of surgery, a urine and blood sample will be collected and alcohol and drug screening labs ordered through the electronic health record. The lab order will include ethyl glucuronide, phosphatidylethanol, and gas chromatography. The results will be shared with the research team and not affect the patient's current surgical candidacy. This measure is exploratory.

Medical Chart Review. The research team will extract and analyze de-identified data from patient's medical records to evaluate the impact of the alcohol brief intervention on perioperative morbidity and mortality. No HIPAA identifiers will be collected from the patient medical record, except dates of treatment and dates of death (if applicable). The dataset will not be linked to patient identifying information. This measure is exploratory.

Post-Intervention Assessment. Participants will also complete brief assessments following intervention completion regarding 4 domains: (1) perceived clinical usefulness (2) personal relevance, and (3) level of engagement, and (4) areas in need of adaptation. The secondary outcome (perception of interventions personal relevance) is gathered here.

Qualitative Exit Interview: After the study is complete (N = 20) participants that indicated willingness to be re-contacted (in consent form) will be asked to complete an exit interview (open-ended researcher-delivered questions) about why they did or did not change their alcohol use, and what the role of the intervention was in that decision making process. The purpose is to further refine the intervention conditions for further development and dissemination. This measure is exploratory.

Intervention Conditions

Health Coaching: Participants randomized to the health coaching condition will be scheduled for two in-person sessions, which will take place approximately 4 weeks prior to surgery. Health coaching will be delivered in person or through an encrypted, university-supported virtual meeting platform, depending on participant preference. Health coaching will use a non-confrontation motivational interviewing (MI) style. Intervention delivery will include expressing concern about unhealthy drinking, providing feedback linking alcohol use and health (related to surgery and general health), advising the patient regarding abstinence or alcohol use reduction, and working with the patient to set a drinking goal if he/she is ready to change. We will also include a personalized feedback component to address the links between pre-operative alcohol use and postoperative morbidity/mortality. All in-person sessions will be digitally audio-recorded and reviewed to ensure the core elements of MI are maintained. The patient will also continue with standard care through the UMHS surgical department. This includes the routine pre-operative assessments, medical appointments, and medical procedures. An infographic about alcohol and surgical health will also be given to participant's at the patient's pre-existing pre-operative clinical visit.

Brief Advice: Patients randomized to the brief advice condition will receive one brief advice session where the patient will receive health information and a resource brochure, but not additional material or motivational interviewing. The patient will also continue with standard care through the UMHS surgical department. This includes the routine pre-operative assessments, medical appointments, and medical procedures. An

infographic about alcohol and surgical health will also be given to participant's at the patient's pre-existing pre-operative clinical visit.

Health Information and Resource Brochure. All randomized participants will receive a brochure including basic information on health behaviors regarding alcohol use, medical misuse of prescription drugs, and information on how to get help for substance use disorders. Women of childbearing age may be included in this study therefore information regarding the risks of alcohol use during pregnancy will be included in the brochure.

6.1 Schedule of Activities

Table 1. Example of a Schedule of Activities (template)

	Pre-screening (Pre-consent)		Baseline Week 1, Day 1	Intervention[1] Week 3	Intervention Week 5	Intervention Week 6 (day or surgery)	Intervention Week 18	Intervention Week 19	Withdrawal[8]
EMR Review eligibility	X								
Eligibility confirmation	X								
Informed consent			X						
Demographics			X						
Outcome Evaluation									
Self-report Alcohol Use			X		X		X		
Alcohol and drug use biomarkers (Urine drug screen and blood draw)						X			
Self-report Drug use			X		X		X		
Mediators and moderators			X		X		X		
Self-report Health and functioning assessment			X		X		X		
Randomization			X						
Experimental Interventions and intervention evaluations			X	X					
EMR review							X		
Qualitative Exit Interview								X	
Event reporting		X	X	X	X	X	X	X	X

Note. All self-report measures are listed in the assessment section

6.2 Description of Activities

6.2.1 Pre-consent activities

We will be screening medical records to determine some patient eligibility criteria such as age, and surgery candidacy. We are requesting a waiver of consent for recruitment purposes. Due to the large number of patients receiving surgical care in the health system, it would be difficult to obtain consent from each patient prior to screening. The risk to patients is minimal in order to allow staff to pre-screen medical records. Patients who are interested in participating will provide informed consent before study activities begin.

Participants who appear eligible after medical record screening will be approached in person or by phone, text or e-mail to complete a short screening survey; participants will provide screening consent prior to the screening survey. Participants eligible after the screening survey will provide informed consent before baseline assessment.

Screen by tablet/online: The screening survey will be administered online using the Qualtrics survey platform. Prior to completing the screening survey, participants will be presented with an online consent form that contains all information typically included in a written consent document including risk, benefits, and security procedures. Before continuing to the survey, participants will provide consent by checking a box.

Screen on the phone: When the screening survey is administered by phone, the staff member administering the screen will obtain telephonic consent from the participant by reading aloud the verbal consent script, and obtaining verbal consent from the participant before beginning the survey. The oral consent script will contain all information typically included in a written consent document including risk, benefits, and security procedures.

6.2.2 Post-consent activities & Outcome Assessments

Outcome assessments are performed three times across an individual's time in the study: baseline, one-month post-baseline (one week prior to surgery, which will be completed online by participants), and four-months post-baseline (3 months after surgery). At approximately 3- months post-surgery, staff will perform a medical chart review (See 6.2.2.1 below). Following brief advice and health coaching sessions, patients will be asked to complete a brief intervention assessment on acceptability and relevance of intervention content.

6.2.2.1 Medical Chart Review. The research team will extract and analyze de-identified data from patient's medical records to evaluate the impact of the two intervention conditions on perioperative morbidity and mortality. We are underpowered to detect potential between group effects of interventions on these outcomes, thus they are not part of our primary aims/hypotheses. No HIPAA identifiers will be collected from

the patient medical record, except dates of treatment and dates of death (if applicable). The dataset will not be linked to patient identifying information.

6.2.3 Randomization and Retention

Computer-generated urn randomization[26] will ensure balanced groups based on gender. Research staff will be blind to participant study condition (with the except of those delivering interventions). We will track participant retention as a measure of study feasibility. Retention strategies include, collecting multiple forms of participant and collateral contact information and sending reminders by e-mail, phone, and text. We aim to retain 80% of patients (72/90) using these strategies and those used in mentors' past research that achieved similar rates of retention.

6.2.4 Control & Experimental Interventions

Intervention and Control Conditions.
See section 5

6.2.5 Outcome Assessments

The change alcohol use and acceptability assessments will occur at three times throughout the study: baseline, one-month post-baseline, and four-months post-baseline. See List of Study Activities Table. We will verify alcohol and drug use reports through a blood draw and urine drug screen conducted on the day of surgery that will undergo lab testing for drug/alcohol biomarkers.

Qualitative Interviews

A total of 20 patients, 10 from each intervention condition, will be selected (based on response vs. non-response to intervention. Response is defined as an alcohol use reduction of greater than one standard deviation from the mean between baseline and final follow-up. Non-response is defined as any increase in alcohol use between baseline and final follow-up or no change in alcohol use. These participants will be asked to complete exit interviews regarding their experience. Qualitative interviews with patients occur during a single interaction with research staff. Qualitative interviews will be audio recorded. We will initially focus our patient interviews on what factors led to change or lack of change in alcohol use, and how the intervention played a role in these changes, and how the intervention could be improved.

6.2.6 Withdrawal

If subjects withdraw or decline to finish treatment, we will make every effort to gather primary outcome data at regularly scheduled follow-ups. We will also query for an adverse event over the phone or in person. For subjects who wish to withdraw completely from the study, we will make every effort to collect the data as soon as possible – i.e. when the individual lets you know of their decision to withdraw. We will continue to use data that was obtained prior to withdrawal date unless the participant asks for it to be destroyed. The data will be kept secure until it is destroyed.

7 SAFETY

7.1 Potential Risks

The risk of violation of confidentiality exists because human participants are giving personal information. This risk is related to the damage that could be caused by an inadvertent release of sensitive information. Risk of a breach of confidentiality is minimal. Participants will be informed of the procedures taken to protect their confidentiality. Questions will be asked about alcohol, prescribed opioid and sedative medications, depression, and physical health. Prior to participating in the study, the consent form will contain a statement explaining mandatory reporting requirements for information reported regarding intention to harm self or imminent harm to others.

Participants could become upset during the intervention or may become uncomfortable as a result of being asked personal questions. All participants, of course, are free to terminate any portion of the study at any time or refuse to respond to any questionnaire item. Information about protecting against this risk are outlined in the next section. The investigators of this project will establish protocols for both research staff to guide them in responding to any crisis or harm situations (see Data Safety and Monitoring Plan). We will not screen participants for suicidality but if it is mentioned in an interview or intervention, further clinical assessment and individualized referral will be provided according to a detailed risk management plan. Note that Dr. Fernandez, Principal Investigator, is a licensed clinical psychologist who will be available to research staff to assist with determination of risk level. Procedures are consistent with those used in prior work in the psychiatry department that have been successfully implemented.

Participants with alcohol dependence could experience withdrawal syndrome if they stop drinking abruptly. We will make every effort to identify patients at risk for alcohol withdrawal at baseline and encourage them to taper alcohol (and drug) use rather than stop abruptly should they chose to reduce or stop use. The pre-operative surgical and anesthesia team also assesses alcohol and drug use for every patient as part of standard care at several time points and enacts the Michigan Alcohol Withdrawal protocol for post-operative withdrawal prophylaxis. Thus patients will be encouraged to share accurate information about alcohol and drug use with their health care providers prior to surgery. We will also encourage admission to substance abuse treatment and/or

use of pharmacology when appropriate. If a patient has symptoms of alcohol dependence or reports past alcohol withdrawal symptoms we will consult with our consulting psychiatrist with expertise in withdrawal management for additional guidance. If we are still concerned about a patient's safety related to alcohol or drug withdrawal, we would inform their surgical/anesthesia healthcare provider of this risk so that proper treatment can be offered perioperatively, and make every effort to let the patient know that we are communicating this information to their provider.

Because some women may not know that they are pregnant or may not disclose their pregnancy, the health brochure given to all randomized participants will include information regarding the risks of alcohol use during pregnancy. In addition, all pregnant women who are using substances will be encouraged to take part in a substance use treatment program.

7.2 Potential Benefits

Participants may benefit from participation in Health Coaching or Brief Advice sessions through alcohol use reduction and improved health. In addition, participants may benefit from the satisfaction of knowing they are contributing to a scientific experiment aimed at gaining knowledge that may help others. Others could benefit from the proposed research to the extent that the information on health services, alcohol screening, and alcohol brief intervention is disseminated and utilized towards prevention and treatment efforts.

7.3 Assessment of Potential Risks & Benefits

The degree of risk to which study participants will be exposed in the proposed protocol is low. By contrast, the potential benefits to the individual and society are substantial, insofar as the results of this study will be used to develop and implement interventions for pre-operative alcohol use. The interventions have the potential to successfully identify and reduce risky drinking prior to life-threatening surgical procedures. They also have the potential to reduce utilization of postoperative healthcare services. When considering the minimal risks entailed with the data collection and tests proposed, in combination with the extensive efforts to limit/eliminate these risks, we feel that the potential benefits to the research community and future interventions far outweigh the potential minimal risks.

7.4 & 7.5 Event Reporting Schedule^{eRsch} and Classification of Adverse Events

Project staff will notify PI of SAEs immediately. All adverse events will be reported to the Institutional Review Board (IRBMED) per standard reporting guidelines; and an annual report will be submitted to the NIAAA Project Officer summarizing all adverse events. Per standard reporting guidelines, related and unexpected SAEs will be reported as soon as possible but within 7 calendar days, related and expected SAEs will be reported within 14 calendar days, unrelated and unexpected SAEs will be reported annually, and expected and unrelated SAEs will not be reported unless they exceed the rate expected for the study population. Dr. Fernandez will be responsible for

determining the severity of an event, and whether such adverse events were expected (i.e. listed as expected in the DSMP or included in the informed consent). The person responsible for reporting adverse events will be Dr. Fernandez; she will also be responsible for reporting amendments to the protocol to IRBMED prior to implementation of any changes.

In the event that a participant either withdraws from the study or the PI decide to discontinue a participant due to an AE or SAE, the participant will be monitored by Dr. Fernandez, PI, via ongoing status assessment until (a) a resolution is reached (e.g., the problem has resolved or stabilized with no further change expected), (b) the SAE is determined to be clearly unrelated to the study intervention, or (c) the SAE results in death. Actions taken by the IRB in response to adverse event will also be reported to the funding agency, as will reports of changes or amendments to the protocol resulting from an adverse event. Outcomes of AEs and SAEs will be regularly reported to NIH and IRB (as outlined above). A summary of the AEs and SAEs that occurred during the previous year will be included in the annual progress report to NIH and the annual IRB renewals at the University of Michigan. Events that do not meet the criteria of an AE or SAE will also be included in the project's annual progress reports to NIH and the University of Michigan IRB.

7.5 Definitions for Adverse Events and Serious Adverse Events[ct.gov;eRsch]

Monitoring, Grading, Documentation, and Reporting of Adverse Events. *It is unlikely that the study protocol will lead to an adverse event (AE) or serious adverse event (SAE). However, we have established procedures for dealing with these events.* In the proposed study we will use the FDA definition of adverse events (AE) and serious adverse events (SAE). An adverse event is any undesirable experience, serious and non-serious, in a participant that may have a causal relationship with study participation. Symptoms or conditions present at or before the study that manifest themselves with the same intensity or frequency after study participation will not be recorded as adverse events. At the time of each contact, all participants will be monitored for the development of adverse experiences. Any concerns will be immediately reported to the PI who will review the information.

7.5.1 Relationship to Participation –

The PI will classify the relationship of the study protocol to the event as:

- *Definitely Not Study-Related*: There is a 0% chance the event is related to the study. It is clear that the participant's clinical state fully explained the event, and not the study protocol.
- *Possibly Study-Related*: There is a 1-49% chance the event is related to the study. The participant's clinical state can explain the event; however, the study protocol could possibly have influenced the event.
- *Probably Study-Related:* There is a 50-99% chance the event is study related. The event follows a reasonable temporal sequence associated with participating in the study and cannot be fully explained by the participant's clinical state.
- *Definitely Study-Related.* There is a 100% chance the event is study-related. The

event follows a reasonable temporal sequence associated with participating in the study and cannot be explained by the participant's clinical state.

7.5.2 Severity of Event

The scale below will be used to estimate the grade of severity of the adverse event:

- *Grade 1 Mild*: Transient or mild discomfort, no limitation of activity, no or minimal intervention/therapy required.
- *Grade 2 Moderate*: Mild to moderate limitation in activity; some assistance may be needed; no or minimal intervention/therapy required.
- Grade 3 Severe: Marked limitation in activity; some assistance usually required; intervention/therapy required; hospitalization possible.
- Grade 4 Life –threatening: Extreme limitation in activity; significant assistance required; significant intervention/therapy required; hospitalization probable (SAE)

7.5.3 Expectedness

Expected adverse events: Given that the population for this study consists of pre-operative patients experiencing varying levels of pre-operative risk, we expect morbidity or mortality from surgical complications, as well as serious and non-serious surgical complications at a rate consistent with the general surgical patient population. Study staff may become aware of these complications during review of medical charts, or from participant self-report during follow up assessments.

7.6 Safety Monitoring

Responsibility for Data and Safety Monitoring. The PI, Dr. Fernandez, with assistance from the mentoring team, will be primarily responsible for monitoring participant safety. The primary concern will be the appropriate referral for patients who experience distress during assessment as well as the protection of client confidentiality. The PI will meet weekly with staff on the project, at which time they will evaluate the progress of the project, including issues regarding data management and participant risk. The PI will meet with mentors at monthly (e.g. Dr. Frederic Blow) to review study progress and any issues that arise. Urgent issues will be addressed immediately.

Data Management. Project staff will be educated on the latest policies regarding the ethical treatment of participants and the protection of confidentiality. Several procedures will be utilized to guarantee the validity, integrity, accuracy and completeness of the data. Data files are accessible only to project personnel and are password protected. Finally, the project database will also be password protected and accessible only to research staff. Files used in data analysis will not have any identifying information in them – just randomly assigned ID numbers. All identifying information will be kept in a separate password protected file. All paper data will be filed in locked cabinets inside locked rooms that only the PI and research staff will have access to. No patient identifiable information will be released or published without written permission unless

required to do so by law.

Entities conducting monitoring. The Michigan Medicine IRB (IRBMED) will review this protocol and all procedures and will provide oversight. Monitoring will be done by the PI, mentors, and IRBMED.

What is monitored? Monitoring is done of all procedures to ensure that they conform to approved protocol; of unforeseen circumstances that might arise and affect safety; of all reports of serious adverse events as defined in 38 CFR 46 (death, new prolonged hospitalization, persistent or significant disability/incapacity, or congenital anomaly/birth defect); of other significant adverse events (adverse events that lead to drop out by participant, termination by the investigator, termination or reduction of treatment); of unexpected adverse events resulting from the study; and of expected adverse events.

Data and Safety Monitoring Plan

Safety Monitoring

The Principal Investigator, Dr. Fernandez, will ultimately be responsible for monitoring the data safety and quality of the study with involvement from the study coordinator. It should be noted that all research projects involving human participants, including the proposed one, require approval from the Institutional Review Board (IRBMED). A Certificate of Confidentiality will be provided for this study from the National Institute on Health (NIH).

Dr. Fernandez will ensure that all relevant IRB policies, procedures and stipulations are being followed. Dr. Fernandez also will be responsible for ensuring that project staff adhere to the IRB policies including: (1) all participants will understand, agree to, and sign a written consent form before participating; (2) strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; (3) the assessments will be completely confidential and no names will be associated with the assessment data; (4) consent forms and identifying information will be kept separately from the participant data; (5) all identifying information (consents, tracking data) will be kept locked at all times and computer files will have restricted access; (6) participants will be informed in writing in the consent form how to contact the PI, the project manager, and IRB office with any questions and/or concerns.

Crisis Assessment: Dr. Fernandez will be responsible for providing training to all research staff regarding procedures for identifying, managing, and responding appropriately to acute warning signs of distress that could occur as a result of the assessments. Such strategies include maintaining an empathic response, acknowledging the distress through reflection, and eliciting or encouraging use of relaxation and cognitive calming strategies. Study staff will receive training from Dr. Fernandez in crisis assessment and management procedures in the event that participants reveal suicidal or homicidal ideation, child physical/sexual abuse, or concerns about safety. These crisis procedures will include a review of the study protocol regarding the limits of confidentiality, how to liaison with study site staff (i.e., in-patient psychiatry, emergency department) to arrange for an assessment, circumstances

in which it may be necessary to notify authorities regarding intent to harm self or others (i.e. participant provider, child protective services), and the development of safety plans and resources. Study procedures also will include immediately paging/contacting Dr. Fernandez in cases in which this may become necessary (or contacting the assigned backup clinician during designated time periods). Dr. Fernandez will be responsible for providing regular supervision to research staff having direct contact with participants including crisis procedures for assessment and referral procedures for participants who meet criteria for suicidality. Supervision will focus on procedures for managing issues that could arise.

In the case that a participant indicates any level of suicidal ideation or recent attempt during encounters with any study staff a suicide risk management protocol will be used. The protocol utilizes an algorithm of scripted risk assessment questions and "action steps" dependent on the participant responses. Based on the level of risk determined by the algorithm, study staff may perform one or more of the following: a) recommend the participant call or be transferred to the national suicide crisis hotline, the University of Michigan's Psychiatric Emergency Services (PES), or the nearest emergency department to immediately address suicide risk and determine whether emergency medical services or police should be activated to conduct a wellness check in the patient's home or community, b) notify a designated on-call study team clinician when the suicide risk management algorithm has been activated, and when any questions arise regarding risk management.

Data Monitoring Plan

The Principal Investigator (PI) ultimately will be responsible for monitoring the data safety and quality with involvement from study coordinator. Data will be collected using the Qualtrics survey platform and or/standardized paper forms and will only be identified with the study ID of the participant. The codes that link the name of the participant and the study ID will be kept separately and securely, along with any signed consent forms obtained. Quality control and reliability of screening, baseline and follow-up assessments will be monitored by Dr. Fernandez throughout the trial via regular meetings and observation of the research staff conducting standardized assessments. Additional data will be stored in a study database created within the REDCap application. The quality of the data will be monitored throughout the study. Data will be analyzed using a data analysis program such as SAS software. Data quality will be monitored by random inspection of the completed forms by the research staff and any problems detected will be discussed with the PI.

Qualitative interviews will be conducted by trained research staff. The qualitative interviews will be audio-recorded. The audio-recordings of the sessions and interviews will be uploaded to a secure network server with restricted access. Once collected, participant data will remain confidential.

8 STATISTICAL CONSIDERATIONS[ERSCH]

8.1 Sample Size

Sample Size and Power Considerations. The sample size (N = 90) was primarily chosen to facilitate conclusions regarding study feasibility, acceptability, and provide experience with study protocol (e.g. recruitment, retention, assessment, and analysis). Participant retention (n = 72; 80%) is achievable using methods utilized in mentor's past research[27,28] and described in the retention section. A final sample of 72 participants will provide power of .80 to detect a medium effect (f^2 = .20) using the proposed analyses. Based on meta-analyses of MI for excessive drinking, medium effects are expected within a 4-month follow up period[29,30]. Between group differences in post-operative morbidity, mortality, and healthcare utilization will likely be 'very small' based on base-rates of postoperative complications. This study is underpowered to detect small effects. For this reason, hypothesis testing is considered 'exploratory.' Therefore, this study will primarily provide pragmatic information and experience with the study protocol to inform a fully-powered RCT.

8.2 Data Analyses[ct.gov]

8.2.1 General Approach

Data Preparation. Prior to analyses, we will examine patterns of missing data, research dropout, intervention fidelity, distributional properties of measures, correlations among outcome measures[31]. Given the small sample, we will pay particular attention to data distribution and use transformations when appropriate.

Data Analysis. We will examine between group effects on alcohol use using General Estimated Equations (GEE). We expect balanced groups on key variables as a result of urn randomization but will test the following covariates for systematic effects on outcome; gender, age, race/ethnicity, surgery type, and drug use. These analyses will use regression modeling using GEE due to the correlated structure of our data from repeated measures at baseline and follow-up. The GEE methodology properly estimates the regression coefficient and variance of the regression coefficient when correlated data are used in regression analysis will use all data available for participants including those subjects lost to attrition. Appropriate distributions will be use used based on the nature and distribution of the response variable. Relevant covariates will be included such as gender, age, race/ethnicity, surgery type, smoking status, and drug use.

8.2.2 Primary Outcome

The primary outcome of this study is between group differences in change in alcohol use from baseline to follow-up. This is defined as change in average weekly alcohol use (quantity by frequency) as measured by the Time Line Follow Back. Our hypothesis is: Relative to the brief advice group, the health coaching group will experience greater reductions in average weekly alcohol use between baseline and follow-up. This

hypothesis is considered exploratory given the low power to detect significant differences.

Qualitative Analysis:

All qualitative interviews will be digitally audio-recorded and transcribed verbatim using a HIPAA-compliant transcription service. Transcripts and codes will be analyzed using Nvivo software. We will analyze data using applied thematic analysis. Emerging themes and data interpretations will be used for intervention refinement.

9 REGULATORY, ETHICAL AND STUDY OVERSIGHT CONSIDERATIONS

9.1 Informed Consent Process[eRsrch]

Except for when identifying potential participants through MiChart, data will be accessed and collected only with informed consent. Consent will be obtained either in writing, over the phone, or online. Signed paper consents will be filed in a locked, confidential research file, or electronically on study provided tablet computers and stored in a secure database. Copies of consent forms will be given to the participant. Unique identification numbers will be assigned to participants who consent. All data forms will be coded with this number rather than with a name. Computer data files will be saved with passwords. Consent forms will be stored separately from other study data because they contain identifying information. Only the participant code number will be entered with the study data. Furthermore, we will receive a Certificate of Confidentiality from the NIH to protect the confidentiality of our data from legal requests.

9.2 Confidentiality and Privacy[eRsrch]

To minimize the risk of breaches of confidentiality, every effort is made to ensure that study data are always confidential, and web- and paper-based data are never stored so that data can be linked to a particular person. Training of research staff will include information about the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants. In addition, all research personnel will complete the required UM confidentially certification training.

9.3 Future Use of Stored Specimens and Data

9.4 Data Handling & Record Keeping

9.4.1 Quality Assurance & Quality Control

Throughout the proposed research investigation, participants' names and contact information will be stored in a secure, password-protected database, separate from their study data. Names will be linked to individual ID numbers *only* in a study database, which will be kept in a restricted access folder on a secure server. Patient audio from intervention sessions and exit surveys will also be kept in a restricted access folder on a secure server. All information collected will be accessible only to research staff who have completed and maintain mandatory training in the protection of human subjects (see 9.4.2)

REDCap will be used to track subject demographics, surgery details, screening scores, and level of study completion. REDCap uses several methods to protect data from vulnerability and exploitation. Incoming REDCap data gets filtered, sanitized and escaped as part of REDCap's security procedures. The study investigators will ensure that Research Assistants (RAs) and other study staff will only have access to the REDCap data and information they need to complete their work by creating and updating user rights in REDCap.

Qualtrics: The project-specific Qualtrics site is protected with a researcher-designated login name and password. The site houses the surveys and compiles data that staff will then transfer to a password protected Access database on the Department of Psychiatry secure network. For the web-based follow-up surveys, participants receive an email invitation inviting them to take the survey on-line and directing them to the Qualtrics site. An additional password may be given to participants in order for them to access to the site. There are systems in place that prevent the survey from being taken by the same user more than once. No identifying information is linked to the participants. There are security precautions in place to protect against unauthorized access, but there is a small risk of unauthorized access. Information regarding Qualtrics security and privacy statements can be found at http://www.qualtrics.com/security-statement and http://www.qualtrics.com/privacy-statement.

An encrypted, university-supported virtual meeting platform (e.g., , Zoom) will be used for delivering ASPIRE interventions via telephone or tele-video. The plaform has a highly secure infrastructure that includes network and application firewalls, DOS protection, and penetration testing. The encrypted, university-supported virtual meeting platforms do not record or store patient information. It encrypts and transmits content via phone that supports HIPAA privacy rules. The ASPIRE study will not keep any patient video, only audio for quality assurance purposes, and transcription and coding in the case of qualitative exit surveys.

Training

All hired members of the research team will complete training and receive certification in Human Subjects Research Protection and HIPAA regulations, and the investigators will keep current certifications up to date. All members of the research team will also complete PEERRS training. All staff shall attend and successfully complete the University of Michigan Recipient Rights training within the first 90 days of employment.

All staff delivering sessions will take part in a two-day motivational interviewing training and weekly meetings with the study PI (a licensed clinical psychologist) to learn both specific intervention content, and MI delivery. They will also listen to audio-recordings of completed sessions from the refinement trial. Interventionists will need to complete at least three practice sessions with other staff. One of these sessions must be audio-recorded and coded with the MI treatment integrity checklist and meet an 80% competency to MI, as well as deliver 90% of elements from the content checklist.

Dr. Fernandez will ensure that all relevant IRB policies, procedures and stipulations are being followed and she will be responsible for ensuring that project staff adhere to the UM IRB policies including the following: (1) All participants will understand, agree to,

and provide consent before participating; (2) Strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; (3) Assessments and interventions will be completely confidential within intervention groups and no names will be associated with the obtained data; (4) Identifying information will be kept separate from the coded participant data; (5) All identifying information will be kept locked at all times and computer files will be saved with passwords on secure servers; and (6) Participants will be informed in the consent form on how to contact the PI and IRB office with any questions and/or concerns. Any serious unexpected and study related adverse events will be reported within 48 hours of learning of the event to the Project Officer and to UM within UM IRB reporting guidelines by Dr. Fernandez in directly supervising research staff, the investigators will be responsible for monitoring these confidentiality procedures. Quality control and reliability of screening, baseline and follow-up data will be monitored via regular meetings where data frequencies are examined. Dr. Fernandez will also monitor the quality of the data files via supervision of the coordinator and data manager.

The investigators will be responsible for providing training to all research staff who are interacting with participants via the intervention regarding procedures for identifying, managing, and responding appropriately to acute warning signs of distress. Staff will receive training in risk assessment as outlined in previous sections.

Management of AEs (See section 7)

9.4.2 Protocol Deviations

Study protocol deviations are not expected and will not be allowed. Any protocol deviations will be addressed, tracked, and reported per the procedure below.

It will be the responsibility of the site investigator to use continuous vigilance to identify and report deviations within 7 working days of identification of the protocol deviation, or within 7 working days of the scheduled protocol-required activity. All deviations will be addressed in study source documents, reported NIAAA Program Official. Protocol deviations will be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator will be responsible for knowing and adhering to the reviewing IRB requirements.

9.4.3 Monitoring

We will monitor through routine data monitoring, weekly review meetings, staff training and annual re-training, and regular record reviews for assuring protocol compliance, and data quality, including regular record review and data double-entry to test for errors in data entry.

10 COMMITTEES

N/A

11 REFERENCES

1. Khuri SF, Henderson WG, Daley J, et al. Successful implementation of the Department of

Veterans Affairs' National Surgical Quality Improvement Program in the private sector: the Patient Safety in Surgery study. *Ann Surg*. 2008;248(2):329-336. doi:10.1097/SLA.0b013e3181823485.

2. Eliasen M, Grønkjær M, Skov-Ettrup LS, et al. Preoperative Alcohol Consumption and Postoperative Complications: A Systematic Review and Meta-analysis. *Ann Surg*. 2013;258(6). doi:10.1097/SLA.0b013e3182988d59.

3. Bradley K a, Rubinsky AD, Sun H, et al. Alcohol screening and risk of postoperative complications in male VA patients undergoing major non-cardiac surgery. *J Gen Intern Med*. 2011;26(2):162-169. doi:10.1007/s11606-010-1475-x.

4. Rubinsky AD, Bishop MJ, Maynard C, et al. Postoperative risks associated with alcohol screening depend on documented drinking at the time of surgery. *Drug Alcohol Depend*. 2013;132(3):521-527. doi:10.1016/j.drugalcdep.2013.03.022; 10.1016/j.drugalcdep.2013.03.022.

5. Oppedal K, Møller A, Pedersen B, Tønnesen H. Preoperative alcohol cessation prior to elective surgery. *Cochrane database Syst Rev*. 2012;(7):CD008343. doi:10.1002/14651858.CD008343.pub2; 10.1002/14651858.CD008343.pub2.

6. Harris AHS, Reeder R, Ellerbe L, Bradley K a, Rubinsky AD, Giori NJ. Preoperative alcohol screening scores: association with complications in men undergoing total joint arthroplasty. *J Bone Joint Surg Am*. 2011;93(4):321-327. doi:10.2106/JBJS.I.01560.

7. Rubinsky AD, Sun H, Blough DK, et al. AUDIT-C alcohol screening results and postoperative inpatient health care use. *J Am Coll Surg*. 2012;214(3):296-305.e1. doi:10.1016/j.jamcollsurg.2011.11.007; 10.1016/j.jamcollsurg.2011.11.007.

8. Pedersen B, Oppedal K, Egund L, Tonnesen H. Will emergency and surgical patients participate in and complete alcohol interventions? A systematic review. *BMC Surg*. 2011;11:26. doi:10.1186/1471-2482-11-26; 10.1186/1471-2482-11-26.

9. Saitz R, Palfai TP, Cheng DM, et al. Brief intervention for medical inpatients with unhealthy alcohol use: a randomized, controlled trial. *Ann Intern Med*. 2007;146(3):167-176.

10. Field CA, Caetano R. The effectiveness of brief intervention among injured patients with alcohol dependence: who benefits from brief interventions? *Drug Alcohol Depend*. 2010;111(1-2):13-20. doi:10.1016/j.drugalcdep.2009.11.025.

11. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. *Addiction*. 1993;88(6):791-804. http://www.ncbi.nlm.nih.gov/pubmed/8329970. Accessed January 30, 2018.

12. Sobell LC, Maisto SA, Sobell MB, Cooper AM. Reliability of alcohol abusers' self-reports of drinking behavior. *Behav Res Ther*. 1979;17(2):157-160. http://www.ncbi.nlm.nih.gov/pubmed/426744. Accessed November 27, 2018.

13. Stockwell T, Murphy D, Hodgson R. The severity of alcohol dependence questionnaire:

its use, reliability and validity. *Br J Addict*. 1983;78(2):145-155. http://www.ncbi.nlm.nih.gov/pubmed/6135435. Accessed November 26, 2018.

14. Feinn R, Tennen H, Kranzler HR. Psychometric properties of the short index of problems as a measure of recent alcohol-related problems. *Alcohol Clin Exp Res*. 2003;27(9):1436-1441. doi:10.1097/01.ALC.0000087582.44674.AF.

15. Flannery BA, Volpicelli JR, Pettinati HM. Psychometric properties of the Penn Alcohol Craving Scale. *Alcohol Clin Exp Res*. 1999;23(8):1289-1295. http://www.ncbi.nlm.nih.gov/pubmed/10470970. Accessed November 27, 2018.

16. LaBrie JW, Quinlan T, Schiffman JE, Earleywine ME. Performance of Alcohol and Safer Sex Change Rulers Compared With Readiness to Change Questionnaires. *Psychol Addict Behav*. 2005;19(1):112-115. doi:10.1037/0893-164X.19.1.112.

17. Breslin FC, Sobell LC, Sobell MB, Agrawal S. A comparison of a brief and long version of the Situational Confidence Questionnaire. *Behav Res Ther*. 2000;38(12):1211-1220. http://www.ncbi.nlm.nih.gov/pubmed/11104185. Accessed February 20, 2015.

18. World Health Organization. The Alcohol, Smoking and Substance Involvement Screening Test (ASSIST): development, reliability and feasibility. *Addiction*. 2002;97(9):1183-1194. http://www.ncbi.nlm.nih.gov/pubmed/12199834. Accessed March 3, 2014.

19. Butler SF, Budman SH, Fernandez KC, et al. Development and validation of the Current Opioid Misuse Measure. *Pain*. 2007;130:144-156. doi:10.1016/j.pain.2007.01.014.

20. Ader DN. Developing the Patient-Reported Outcomes Measurement Information System (PROMIS). *Med Care*. 2007;45(Suppl 1):S1-S2. doi:10.1097/01.mlr.0000260537.45076.74.

21. Bohnert ASB, German D, Knowlton AR, Latkin CA. Friendship networks of inner-city adults: a latent class analysis and multi-level regression of supporter types and the association of supporter latent class membership with supporter and recipient drug use. *Drug Alcohol Depend*. 2010;107(2-3):134-140. doi:10.1016/j.drugalcdep.2009.09.012.

22. Doljanac RF, Zimmerman MA. Psychosocial Factors and High-Risk Sexual Behavior: Race Differences Among Urban Adolescents. *J Behav Med*. 1998;21(5):451-467. doi:10.1023/A:1018784326191.

23. McLellan AT, Kushner H, Metzger D, et al. The Fifth Edition of the Addiction Severity Index. *J Subst Abuse Treat*. 1992;9(3):199-213. http://www.ncbi.nlm.nih.gov/pubmed/1334156. Accessed November 28, 2018.

24. French MT, Dunlap LJ, Zarkin GA, McGeary KA, Thomas McLellan A. A structured instrument for estimating the economic cost of drug abuse treatment. *J Subst Abuse Treat*. 1997;14(5):445-455. doi:10.1016/S0740-5472(97)00132-3.

25. Wetsch WA, Pircher I, Lederer W, et al. Preoperative stress and anxiety in day-care patients and inpatients undergoing fast-track surgery. *Br J Anaesth*. 2009;103(2):199-205. doi:10.1093/bja/aep136.

26. Stout RL, Wirtz PW, Carbonari JP, Del Boca FK. Ensuring balanced distribution of prognostic factors in treatment outcome research. *J Stud Alcohol*. 1994;Supplement:70-75.

27. Borsari B, Hustad JTP, Mastroleo NR, et al. Addressing alcohol use and problems in mandated college students: a randomized clinical trial using stepped care. *J Consult Clin Psychol*. 2012;80(6):1062-1074. doi:10.1037/a0029902.

28. Borsari B, Carey KB. Two brief alcohol interventions for mandated college students. *Psychol Addict Behav*. 2005;19(3):296-302. doi:10.1037/0893-164X.19.3.296.

29. Havard A, Shakeshaft A, Sanson-Fisher R. Systematic review and meta-analyses of strategies targeting alcohol problems in emergency departments: interventions reduce alcohol-related injuries. *Addiction*. 2008;103(3):368-76; discussion 377-8. doi:10.1111/j.1360-0443.2007.02072.x.

30. Rubak S, Sandbaek A, Lauritzen T, Christensen B. Motivational interviewing: a systematic review and meta-analysis. *Br J Gen Pract*. 2005;55(513):305-312. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1463134&tool=pmcentrez&rendertype=abstract.

31. Fidell LS, Tabachnick BG. Preparatory data analysis. In: Shrinka JA, Velicer WF, eds. *Handbook of Psychology: Research Methods in Psychology, Volume 2*. New York: John Wiley & Sons; 2003:115-141.