Full Study Title: Behavioral Economic Treatment to Enhance Rural Living

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Principal Investigator: Lara N. Coughlin, PhD

Study Protocol
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Principal Investigator: Lara N. Coughlin, PhD

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Background

Risky alcohol use (i.e., AUDIT-C[1,2] ≥3 in females and ≥4 in males), increases risk for adverse health outcomes (e.g., injury,[3] impaired driving,[3] or alcohol use disorder[4]). Risky alcohol use is wide-spread,[5] economically burdensome,[6] and under-treated in healthcare settings.[7,8] Research is needed to develop more effective and scalable interventions with improved reach to reduce this public health burden.

Risky drinking in rural regions. Rural drinkers exceed recommended daily alcohol use limits at higher rates[9] and have greater symptom severity[10] than urban/suburban counterparts. Compounding the problem, interventions in rural areas are more costly,[11] of lower quality,[12] and less accessible.[13] Sparsely populated rural areas face barriers beyond access. To be successful, interventions must overcome challenges such as social and geographical isolation, limited availability of alternative, healthier behaviors, and resource poor lifestyles.[14–17] Personalized interventions can overcome these barriers by providing relevant content despite contextual limitations. Primary care is an excellent setting for identifying risky drinkers eligible for mobile health (mHealth) early interventions, reducing the need for more intensive future treatment.[10,18,19] Remotely-delivered interventions provide feasible, potentially low-cost means for reaching rural adults.[20] Due to the shrinking digital divide,[21,22] cell phone use is nearly ubiquitous (91% of rural Americans own cell phones).[23] Text message and phone-based modalities are recommended for rural interventions where app- and web-based options meet technological shortfalls.[24] *We propose to develop a text-based personalized intervention specifically to reduce risky drinking in rural adults.*

Risky drinking as a reinforcer pathology. Behavioral economics (BE) is theoretically established in addiction research, with strong empirical support and objective assessment tools. To date, however, BE has infrequently been applied to prevention interventions, yet BE may be critical for a new generation of enhanced early interventions for at-risk groups. *Reinforcer pathology*, a BE theory of addiction, posits that problematic alcohol use is related to the overvaluation of alcohol relative to alternative behaviors and undervaluing future reinforcement from alternative behaviors relative to the immediate reinforcement of drinking. Reinforcer pathology can be measured through two distinct but intersecting processes: *excessive demand*, or the persistently high valuation of a reinforcer measured via the Alcohol Purchase Task, and *excessive delay discounting*, or the excessive preference for immediate reinforcement measured via the Delay Discounting Task (see **Fig. 1**). Rigorous prior research, using well controlled, experimental studies support the phenomena of increased demand and excessive future discounting as hallmarks of addiction.[25–30] For example, compared to non-problematic drinkers, non-treatment seeking heavy drinkers exhibit greater alcohol demand at a minimum price (i.e., demand intensity),[31,32] less sensitivity to price increases (i.e., inelastic demand),[31,32] and greater discounting of the future than non-problematic drinkers.[25]

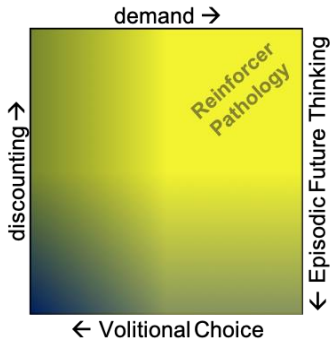

Figure 1: Conceptual model of reinforcer pathology and candidate intervention components

Behavioral Economic Treatment to Enhance Rural Living (BETTER Living). Mobile health interventions have great potential to increase access and quality of care but have not yet met this potential due to a failure to test key theoretical concepts outside of lab settings and in clinical populations as well as a need to develop and test interventions using mHealth to minimize loss of effectiveness on translation.[33] Considerable evidence implicates BE processes in the progression and maintenance of disordered substance use; however, development and

testing of BE interventions to intervene with and repair reinforcer pathology is very recent.[34–3637–39] These interventions have largely focused on *either* diminishing demand for alcohol *or* reducing discounting. A critical gap exists in that BE interventions have been studied largely in isolation from one another, despite the theoretical basis of reinforcer pathology suggesting a need for combined interventions (**Fig. 1**). Because reinforcer pathology is a multicomponent phenomenon, developing multicomponent interventions to target both processes may be most effective. Therefore, we propose to develop and assess acceptability/feasibility of two remotely-delivered intervention components and evaluate the degree to which they modulate hypothesized BE processes (i.e., demand and delay discounting) to repair reinforcer pathology and curb alcohol use. Both interventions components proposed here, Volitional Choice (VC) and Episodic Future Thinking (EFT), include personalized statements suited for mHealth delivery via text message.

Interventions

EFT identifies and describes positive, non-alcohol related events at future time points to facilitate extension of temporal consideration toward future-focused perspectives (e.g., "A month from now I'm going to take my kids to the fair where we will eat cotton candy and ride the Ferris wheel.") In laboratory studies, EFT improves alcohol-induced deficits in prospective memory,[40] reduces alcohol consumption,[41] and decreases delay discounting and demand intensity,[41,42] but does not change other demand metrics.[41,42]

VC creates structured if-then plans to dismantle context-linked alcohol use. VC, informed by the transtheoretical model of behavior change,[43] facilitates alternative, healthier choices by identifying and linking risky cues with alternative actions.[44] (e.g., "If I feel like drinking after a stressful day, then I'll watch Netflix and lift weights instead," "If I'm home alone and tempted to go buy beer, then I will head outside and work on my car instead."). VC identifies healthier alternative strategies to substitute for alcohol use. VC reduces alcohol use in risky drinking college students and our prior shows similar reductions in adults.[45–47]

VC and EFT statements will be collaboratively personalized with participants during a phone-based mid-way session for twice daily text message-based delivery over a 2-week period. The collaborative, highly personalized, and deliberate identification of risky drinking contexts and alternative strategies, in VC, and positive future events, in EFT, to construct these statements is critical in rural environments where alternatives are scarce, resources are limited, and isolation both, geographically and socially, is common.[14–17] Through iterative, participatory-based intervention development and refinement (Aim 1) and a pilot randomized controlled trial (RCT) in the target rural population to maximize likelihood of future translation (Aim 2), we will harness the largely untapped potential of mHealth and address weaknesses of prior BE interventions by setting the stage for a future multicomponent intervention proposal to reduce risky drinking via repair of reinforcer pathology.

The guiding framework for this intervention can be found in Figure 1.

Objective

The specific aims of this project are to:

Research Aim 1: Conduct participatory-based intervention development to adapt and refine VC and EFT for remote delivery to rural risky drinkers through field and focus testing.

Research Aim 2: Employ a randomized controlled trial of the intervention components (N=85).

2a: Evaluate technical feasibility of procedures, intervention components, and mobile delivery methods.

2b: Assess acceptability of intervention components (satisfaction, perceived usefulness, and engagement).

Aim 2 Methods

Enrollment

Target enrollment is up to 85 adults residing in rural-designated area (e.g., county, zip codes) with at-risk alcohol use.

Recruitment Procedures

Research assistants (RAs) will recruit patients in-person at clinic appointments or remotely (phone, text, email or postal mail) after identification via reviewing the EHR for participants who may be eligible for the study **(waiver of consent and HIPAA waiver are requested for this).**. Research staff will review records of patients who reside in rural areas (e.g., Shiawassee county). Results of record reviews will be kept in a screening log, which identifies which records have been reviewed, the preliminary eligibility of the patient, and the outcome of the contact with research staff (e.g., approached/called, enrolled, declined, ineligible, etc.). Staff review the EHR for indication that the participant may be excluded prior to approaching them (e.g., acute psychotic episode and unable to provide consent, currently pregnant) in order to limit the number of people approached who would not be eligible. To be eligible for screening, the patient must be 18 years or older, understand English, able to provide informed consent (medical/physical state does not preclude consent), and reside in rurally designated area. For in-person recruitment, RAs will approach patients in the clinic (e.g., waiting room) for consent to self-administer a brief web-based screening survey on iPads (paused during medical care). For remote recruitment, RAs will reach out to patients by phone, text, email or postal mail using a standard recruitment script adapted from previous studies which describes our study as one which is focused on health, well-being, and risky behaviors (i.e. use of alcohol, consequences of use). Interested participants will be asked to give verbal screening informed consent or complete an online screening consent form in Qualtrics (**waiver of documentation is requested)** and, after consent is obtained, will complete a 3-minute screening survey. Participants screened in person will receive a gift valuing $1.00 for survey completion (e.g., crossword puzzle book, deck of cards, lotion, etc.)

Participants will also be recruited using flyers. Potentially eligible participants who contact the study team will be screened remotely (phone, text, email) for eligibility screening.

Those meeting eligibility criteria (see below) on the screening survey will be eligible for the baseline session. Those interested in participating will have the option to complete an online baseline consent form (for remote recruitment) or review the consent with a RA (in person or by phone; **waiver of documentation is requested**). Interested participants will begin baseline activities after providing consent.

Study Eligibility Criteria

Inclusion criteria: (1) adults (ages 18 and older) presenting in primary care and (2) home address in a rural area (e.g., zip code, county), and (3) an AUDIT-C score of ≥3 in females or ≥4 in males and (4) regular access to an internet-enabled device (e.g., smartphone, computer, tablet). Exclusion criteria: (1) Does not understand English; (2) currently pregnant; (3) unable to provide informed consent due to medical/psychiatric reasons, (4) currently in treatment for a substance use disorder. Potential participants may be excluded based on participant best interest (e.g., if patient has plans to move out of the country during the study period; adult patient with a legal guardian; actively enrolled in another behavioral intervention research study, given the potential confounding effect of receiving multiple interventions on study outcomes; or if study staff know a patient or their family personally, in order to fully ensure participant privacy), with PI approval.

Study Procedures

After enrolling in the study, participants will complete a ~1 hour baseline session (remotely via Qualtrics and/or by phone using a mailed/emailed copy of the survey), including a

15–20-minute Timeline Follow-Back (TLFB), a delay discounting task, alcohol purchase task, measures about anxiety, depression, food craving, motivation to change alcohol use, mindfulness, impaired driving, alcohol use severity, other substance use, consequences of alcohol, and consideration of future consequences (see list of measures below). Participants will be compensated $30 for completion of the baseline session.

Following completion of the baseline assessment session, participants will be invited to complete a mid-way session by phone or video chat, for which they will be randomized to one of four conditions (episodic future thinking, volitional choice, both episodic future thinking and volitional choice, or monitoring only). Randomization of participants to condition will be balanced by age and sex, and participants will be enrolled in the study after randomization. The mid-way session may be audio recorded and will last approximately 30 minutes during which time participants will identify personally-relevant reminders, or cues, that they will receive via text-message over the following 2-week field testing period for all active conditions, in the monitoring only condition participants will receive general psychoeducation about alcohol use, mental health, resources, and a description of the assessments to be completed over the 2-week field testing period. Intervention cues developed by participants (e.g., "If I am thirsty for a beer, then I will have a Coke instead") may be included in the mid-way session as examples for future participants to help participants develop personally useful intervention cues. Participants will be compensated $30 for completion of the mid-way session.

During the 2-week field testing period, participants will receive up to 3 text messages/day including both assessment messages (e.g., How many drinks did you have yesterday?) and intervention messages (i.e., based on the personalized intervention cues developed during the mid-way session). Participants will be compensated up to $42 for responding to daily messages ($3/message x 1 assessment messages/day x 14 days).

Following the intervention, participants will be compensated $35 for completing a ~1 hour post-test/focus testing session, $40 for completing a follow-up assessment at 2-months (mirroring baseline assessment), and $25 for completion of all surveys and at least 90% of text-based assessments. Assessments may be completed by phone/video chat and/or remotely via Qualtrics, based on participant preference. Assessment reminders will be sent in a variety of ways which may include via e-mail, text message, social media private message, mail and/or phone call.

Measures will include reliable, valid measures from prior work:

Screening measure

Alcohol use frequency, AUDIT-C[1,2]

Baseline measures

Demographics questionnaire
Gun Carriage [48]
Locations they drink most
Drug Use Questionnaire
Rural Identity Scale
Cognitive Regulation Questionnaire

Baseline, Post-test and Follow-Up measures

Hypothetical delay discounting task [25,28]
Activity Level Questionnaire[54]
Hypothetical alcohol purchase task [55]
Anxiety scale, GAD-2 [57]
Depression scale, PHQ-2 [58]

WHOQoL-Brief
Food insecurity
Food cravings scale [59]
Nicotine use questionnaire
CUDIT-R
Importance, Self-efficacy, Intention rulers [56]
Mindfulness Attention Awareness scale [63]
Sleep quality measure
Loneliness measure
Pain, Enjoyment of Life, and General Activity Scale
Impaired Driving [60]
Alcohol use severity, AUDIT [51]
Consideration of Future Consequences [62]
Drinking Motives Questionnaire (DMQR)
Penn Alcohol Craving Single Item
Alcohol use frequency, Timeline Follow-back [52,53]
Alcohol use consequences, SIP-R [61]
Acceptability and satisfaction questions

Daily-level assessments
Prior day alcohol use (daily)
Adaptive brief delay discounting task [64]
Substance-free-activities-Brief
Brief Alcohol Demand Task [65]

Data Management and Statistical Design

Data entry methods

The majority of data in this study are obtained via web-based Qualtrics surveys which will be downloaded to secure servers. Qualtrics surveys will be administered by research staff over the phone or via text-message. Data entry will take place for participant tracking (e.g., assigned condition) using databases on our secure servers, and text-message logs will also be entered into databases on our secure internal servers. Manually entered data will be double-entered and checked during quality-assurance procedures

Data analysis plan

Aim 2. Feasibility and acceptability of the intervention, including retention and engagement, participant satisfaction, daily data response rates, and qualitative participant impressions will be collected. Descriptive analyses will be used to inform future adjustments to the intervention to increase feasibility and acceptability.

Power Analysis: We are not powered for efficacy as the primary goal of this proposal is to develop and prepare the intervention through evaluation of feasibility and acceptability for future optimization in larger studies.

Effect Size*:* The novelty of translating the behavioral economically-informed interventions for technology-based delivery necessitates preliminary preparatory studies. This study will provide acceptability and feasibility data and will assist in identifying preliminary moderators and mechanisms of behavior change. We have no basis for listing an expected effect size. Because pilot studies are not powered for efficacy, we will examine if the pattern of change is in the

desired direction and quantify the uncertainty in effect size estimates using 95% confidence intervals.

Data Safety Monitoring Plan

Responsibility for data and safety monitoring

The investigators will be responsible for monitoring the trial and data quality and safety. Dr. Coughlin (PI) will ensure that all relevant IRBMED policies, procedures and stipulations are being followed and she will be responsible for ensuring that project staff adhere to the UM IRBMED 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 confidential and no names will be directly associated with the obtained research 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 IRBMED office with any questions and/or concerns. 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.

Data Confidentiality Plans

Our study team will take the following steps to minimize potential confidentiality breaches. As done in prior research and deemed HIPAA compliant by the IRBs at University of Michigan (U-M) by use of a waiver of HIPAA authorization, minimal clinical data will be collected on patients who refuse to participate in the screening survey, and on patients who the research assistants fail to contact. The mid-way session and post-test/focus testing interview may be audio-recorded to ensure fidelity and audio recordings will be destroyed after the conclusion of the study.

For each stage of the proposed research investigation, participants' names and contact information will be stored in a secure, password-protected database, separate from their study data and only accessible to members of the research team for research purposes. Any paper documents (e.g., patient tracking log) will be stored in locked file cabinets only accessible to study staff, separate from study data. Any additional documents with identifying information linked to individual ID numbers will be only accessible by study staff and stored separate from study data, and in locked file cabinets or in restricted access folders on a secure server (e.g., U-M Dropbox) and destroyed at study completion.

All study cell phones will be password protected and only accessed by study staff who have completed and maintained mandatory training in the protection of human subjects and good clinical practices.

Reporting of AEs and SAEs, Management of SAEs and Other Study Risks

Dr. Coughlin (PI) will be responsible for distinguishing severity of and reporting adverse events. Potential adverse events that could be associated with the research include, but may not be limited to: breaches of confidentiality (addressed above), suicide threats, reports of acts of violence and child abuse (child abuse will also be reported to Children's Protective Services and the consent form includes information to this effect), complaints about the study or the study's research team, and serious or untoward agitation during any study activity. During the informed consent process, participants will be told of the procedures regarding the monitoring of study-related adverse events. The timing of the reporting of any at least possibly study-related adverse event to the U-M IRBMED will be dependent on the severity of the event, and whether

such adverse events were expected (included in the informed consent) and/or related or unrelated to the research. According to U-M IRBMED, all adverse events must be reported for those defined as: “An adverse event is any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio.” 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 U-M within U-M IRB reporting guidelines. Non-threatening potentially serious adverse events that are causally related to the research will be reported to the IRBMED within 7 days of learning of the event. A summary of adverse events that occurred during the previous year will be included in the annual progress report to NIAAA.

Quality Assurance

Quality assurance and reliability of screening, baseline, post-intervention, focus testing, and follow-up assessments will be monitored by Dr. Coughlin throughout the study via regular meetings and observation of the research staff conducting standardized assessments and throughout the study via regular meetings. Dr. Coughlin will monitor the quality of the data files via supervision of the research assistants and data analyst. Data discrepancies will be corrected by a supervisor, based on source documents. The quality of the data will be monitored throughout the study. Data will be analyzed using a data analysis program such as R software. Data quality will be monitored by random inspection of the completed electronic forms by the research assistants and any problems detected will be discussed with Dr. Coughlin. Study staff will receive standardized training in conducting assessments and interventions over the phone/by video chat. Adherence to assessment protocols will be monitored with supervision with Dr. Coughlin. All study staff will receive ongoing training. The mid-way session and focus testing/post-test interviews may be audio-recorded for transcription to ensure consistency and fidelity. The audio-recordings of the mid-way sessions and focus testing interviews will be destroyed after the files are uploaded to a password-protected, secure server with restricted access for transcription. Once collected, participant data will remain confidential. Monthly, Dr. Coughlin, with the help of a research assistant, will review collected data for accuracy and out of range values; ensure that all collected data are backed-up; ensure that all assessment sessions are accounted for in the tracking database; update flow chart to ensure accurate numbers of assessments recorded as completed, missed, refused, or withdrawn

Study Discontinuation Protocol

The PI will work directly with NIAAA, in the case that project discontinuation is necessary. Should there be clear evidence of harm to the participants due to this trial we will cease the trial. Given this is a no more than minimal risk to participants, we do not anticipate evidence of harm. As this is a feasibility/acceptability trial, we do not anticipate being able to detect a treatment effect and thus do not anticipate stopping the trial due to evidence of futility or benefit.

Protection of Human Subjects

The research conducted in Aim 2 does meet the definition of a clinical trial. A Certificate of Confidentiality will be automatically provided by the NIH. All hired members of the research team will complete training and receive certification in Human Subjects Research Protection and HIPAA regulations, including Good Clinical Practice, and the investigators will keep current certifications up to date.

Subject Population, Inclusion/Exclusion Criteria

This protocol involves two separate research studies with similar inclusion/exclusion criteria and study procedures. Target enrollment for **Aim 2** is approximately n=85, which is highly feasible given ample patient flow.

Patients are eligible for screening if they: (1) are adults (ages 18 and older) in primary care of a Healthcare system and (2) have a home address in a rural area (e.g., county or zip code). Additional baseline inclusion criteria include: (3) an AUDIT-C score of ≥3 in females or ≥4 in males and (4) regular access to an internet-enabled device (e.g., smartphone, computer, tablet).

Exclusion criteria: (1) Does not understand English; (2) currently pregnant; (3) unable to provide informed consent due to medical/psychiatric reasons, (4) currently in treatment for a substance use disorder. Potential Aim 2 participants may be excluded based on participant best interest (e.g., if patient has plans to move out of the country during the study period; adult patient with a legal guardian; actively enrolled in another behavioral intervention research study, given the potential confounding effect of receiving multiple interventions on study outcomes; or if study staff know a patient or their family personally, in order to fully ensure participant privacy), with PI approval.

To increase minority representation, we plan to oversample minorities who are African American and Hispanic (~20%) by prioritizing recruitment of minority participants (e.g., prioritizing screening of minority patients). We expect the racial ethnic composition to be ~74% White, 20% Black or African American, 3% Asian, 1% Native American/Alaskan Native, 1% Hawaiian/Pacific Islander, and 1% more than one race and 20% Hispanic. To ensure both sexes are represented, we will oversample females to enroll approximately equal numbers of men and women to be stratified across study conditions.

Recruitment and Consent Procedures

Prior to approaching participants in both aims, study staff will use preparatory electronic health record review to identify potentially eligible participants seen in primary care, including UM Brighton Health Center, in the past 2 years **(waiver of consent and HIPAA waiver are requested for this)**.

For **Aim 2,** participants identified during EHR review may be approached remotely (phone, text, email or postal) or in-person at clinic appointments. Potentially eligible participants may contact the study team after reviewing/receiving a flyer. For feasibility reasons, we are requesting a **waiver of informed consent documentation** to give participants recruited remotely multiple options for providing screening and baseline consent (e.g., verbal consent for those completing screen and/or baseline over the phone; completing an online consent form in Qualtrics for those self-administering the survey(s) on a personal device). After screening consent is obtained, participants will complete a 3-minute screening survey. Those eligible will be invited to review the baseline consent. After providing baseline consent, participants will be invited to complete a baseline assessment (remotely via Qualtrics and/or by phone/video using a mailed/emailed copy of the survey) followed by randomization to study condition (Volitional Choice (VC), Episodic Future Thinking (EFT), VC/EFT, or monitoring only), at which point participants will be enrolled in the study. All participants will complete a mid-way session by phone or video chat prior to the 2-week intervention period. During the 2-week field testing period, participants will receive up to 3 text messages/day every day including both assessment messages (e.g., How many drinks did you have yesterday?) and intervention messages (i.e., based on the personalized intervention cues developed during the mid-way session). Following the intervention, participants will complete a post-test and 2-month follow-up assessment and will be compensated for their time.

Materials

Data will be collected only after participants provide informed consent. Assessment instruments have been used widely in other settings and evaluated for their appropriateness with adult participants. Four primary sources of data exist for this study: 1) participants will self-administer or respond via phone/video-administered sessions to questionnaires to gather pre-intervention, post-intervention, and follow-up data pertaining to demographics, intervention acceptability and feasibility, behavioral economic indices (delay discounting and alcohol demand), alcohol use, and other risk behaviors (e.g., substance use); 2) interventions may be audio recorded for internal quality assurance purposes; 3) daily data will be collected during the 2-week intervention period pertaining to behavioral economic indices and alcohol use (self-report); and 4) qualitative data collected during the post-test/focus testing session may be audio recorded and transcribed to capture intervention acceptability.

Potential Risks

The proposed study poses minimal risks. Every effort will be made to ensure that study participants are protected from risks. The major risk for participants in this study is the violation of confidentiality. This risk is due to the disclosure of personal information regarding the use of alcohol and other substances and is heightened due to the audio recording of the mid-way session and focus testing/post-test interview and possible completion of the mid-way session over video chat. The informed consent will contain a statement about exceptions to confidentiality which include if the participant expresses suicidality, homicidality, or the physical or sexual abuse of a child. We expect that participants will not disclose such information as part of completing the study activities since our assessments and intervention do not specifically inquire about these topics, but should information to this effect be shared, we will provide appropriate referrals to resources and follow appropriate reporting procedures. Study staff will review limits of confidentiality at enrollment, will always notify participants when mandatory reporting or breaking of confidentiality is required, and will only disclose the minimum information necessary as required by law.

We expect that participants will <u>not</u> disclose such information in the context of a mobile health study, but should information to this effect be shared as part of study interaction via in-person, phone, or text-based communication with study staff, Dr. Coughlin, in consultation with her mentors, will provide appropriate referrals to hotlines and local county resources and follow appropriate reporting procedures. We will notify participants when/if we must make any mandatory reports based on information they disclose and we will only disclose the minimum information necessary. Participants will be informed in the consent documentation about the procedures taken to maintain and protect their confidentiality. We will inform participants that during their participation, the text messages are saved for data collection purposes and will be stored on our internal, restricted-access servers in password protected databases. Participants under legal drinking age (those 18 to 20 years old) will be also informed of potential risks of joining a study collecting information about illegal alcohol use including that information about alcohol use will be collected remotely (participants report number of drinks per day in a text message) and stored on password-protected servers.

We will also encourage participants to use a password/code on their phones and to view study assessments and intervention text-messages in private spaces. Participants who complete the midway session by video chat will be informed that they can choose the program most convenient for them to complete video procedures, including HIPAA-compliant programs, and that the study cannot control changes in future policies and potential secret recording with release of audio or video interaction from other programs (e.g., Skype, Facetime). Participants will also be informed that we will take steps necessary to secure their data. Survey data collected will be stored in secure, password-protected databases on the secure U-M network (e.g., U-M Dropbox). When completing intervention sessions or sending text-messages, staff will do so in private spaces and use privacy screens where others who are not part of the

research team could not see the data. Study cell phones used to send text-messages will be password protected. The computerized surveys are designed and administered using Qualtrics Research Suite through the University of Michigan (http://www.qualtrics.com/), which meets the HIPAA standards, and is where data will be stored based on study ID securely and separate from any identifying information.

Participants could potentially experience emotional discomfort as a result of being asked personal questions or because of intervention content. All participants will receive crisis/referral information via a national resource listing that will be shared in person or emailed/mailed (based on participant preference) during remote recruitment to all participants at the time of the baseline session assessment. The resource list will include national resources including suicide hotlines/text-lines, mental health and substance use treatment, etc. All participants will also be notified that they are free to terminate the assessments at any time or refuse to respond to any item.

Protection Against Risk

To minimize the risk of violating confidentiality, research staff will make every effort to ensure that study data are always kept confidential. Staff training procedures will include information about the importance of confidentiality and techniques to maintain confidentiality of all information reported by research participants. Staff will maintain human subjects and confidentiality certifications through the U-M Program for Education and Evaluation in Responsible Research and Scholarship system and will complete CITI Good Clinical Practice Training. Staff will be trained to conduct phone- and video-based sessions where no one can overhear the conversation. Consent documents will fully explain the study procedures, potential risks, and potential benefits.

Unique identification numbers will be assigned to participants. Any data forms will be coded with this number, rather than with a name. The audio-recordings of the mid-way sessions and focus testing/post-test interviews will be destroyed after the files are uploaded to a password-protected, secure server with restricted access for transcription. Computer data files will be saved with passwords on a secured network, and will not contain names, birthdates, etc. See “Data Confidentiality Plans” above for further information on protection of participants’ data. Furthermore, because of the sensitive nature of the data collected, this study is covered by a Certificate of Confidentiality from the NIH to protect the confidentiality of our data from legal requests. Finally, specific information collected during this research study will not be available for use outside of research purposes. Likewise, specific information collected during this research study will not be available to family or friends or others outside of the study team, only staff members who need to know personal identifying information will have access to this information. All data will be collected specifically for use on this project.

Research staff will be trained to respond to any emotional distress and to refer participants to appropriate resources as necessary. All participants are free to terminate the study at any time. Participants can also refuse to respond to any questionnaire item; although some survey items will require a response (e.g., to determine study eligibility), participants who self-administer the survey can choose to exit the survey if they would prefer not to answer these questions. Further, the risk of potential coercion is minimized by using standard recruitment scripts to avoid undue influence. All baseline eligible participants will also receive substance use and mental health resources in a community resource brochure at baseline.

Participants’ confidentiality will be breached by the research study only to protect the safety and welfare of research participants and only in accordance with state and federal law. Staff will receive training in crisis assessment and risk management procedures in the unlikely event that participants reveal suicidal and/or homicidal ideation, or child physical/sexual abuse during study interactions (including via text-message). If staff becomes aware of any of these issues, they will follow our standard risk assessment guidelines for attempting to contact

participants remotely (e.g., message/text/email hotline number and by phone). In cases of psychiatric distress, staff are trained in strategies that include contacting the individual non-judgmentally, using active listening skills, and empathically encouraging use of referral information or other coping skills. Staff will immediately page Dr. Coughlin or one of Dr. Coughlin's mentors for consultation in cases where participants express moderate or acute risk. Staff will also be trained to manage responses to potentially inappropriate messages from participants (e.g., asking on dates, sending explicit image).

Vulnerable Subjects

We will enroll adults residing in rural areas with risky drinking. Vulnerable subjects (e.g., fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals) are not targeted for recruitment in this proposed research. This protocol does not allow for currently pregnant women to be included in the study, because some women may not know they are pregnant or may not disclose their pregnancy, information regarding the risks of alcohol use during pregnancy and a special notation of a local substance use treatment center that has specialized women's program (e.g., Odyssey House) will be provided in the resource brochure provided to all participants at screening. All women who report that they are pregnant and who are using alcohol will be referred this substance use treatment program. This protocol does not include the participation of minors (<18 years old) whose developmental stage would require different intervention content.

Potential Benefits of the Proposed Research to Human Subjects and Others

Participation in the proposed study could potentially benefit participants in a few important ways. First, it is possible that the assessments may be beneficial to all participants by asking them to review their substance use. Therefore, these assessments may actually serve as a very minimal intervention (as could any study with questions that prompt participants to consider and monitor their risky behaviors). Second, all participants will receive referral information for substance use and mental health treatment. In sum, potential benefits for the research outweigh the risks for the participants. Further, with regard to benefits to others, in the event that the intervention tested in the present study is efficacious, the potential benefits to society involve reducing the public health burden associated with alcohol use by way of healthcare expenditures, reductions in impaired driving/motor vehicle crashes, etc. and increasing available services for rural-residing individual with risky alcohol use.

Importance of Knowledge to be Gained

Excessive alcohol use is the 3rd leading preventable cause of death in the U.S., and is associated with significant economic burden and negative health-related consequences that are undertreated in rural areas. By refining and evaluating acceptability and feasibility of two remotely-delivered intervention components using remote text message delivery, the study will contribute to the development of a well-specified, novel mobile health intervention for rural risky drinkers. Given the high rates of mobile phone ownership, if the efficacy is established, this intervention will have great promise for increasing access to alcohol intervention services for rural individuals, thereby benefiting public health. The risks to participants are reasonable in relation to the importance of this knowledge to be gained and potential public health impact of developing an effective treatment to reduce the use of and consequences associated with alcohol use among rural adults.

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