Examining Alcohol Consumption, Perceptions, and User Experience of Alcohol Moderation Strategies

NCT Number: 04286867

Date: 5/11/2023

KENT STATE UNIVERSITY

CONTINUING/ANNUAL REVIEW FORM

INSTRUCTIONS for INVESTIGATORS:

1. **Level II research**: complete this form to request transfer to a three-year approval interval. At the IRB's discretion, certain level II studies may not be transferred to three-year intervals; examples include:
   a. Level III projects
   b. A grant or contract requires annual review
   c. DOD and DOJ funded studies
   d. FDA regulated research
   e. NIH funded clinical trials
   f. Longitudinal studies lasting more than three years
   g. New risks have been identified
   h. Adverse events or an unanticipated problem involving risk to subjects
2. **Level III research**: must be reviewed at the interval determined by the IRB, at least annually. Investigators are responsible for fulfilling requirements associated with continuing review in time for the IRB to carry out review prior to the expiration date of the current IRB approval.
3. Submit this completed document via email attachment to RESEARCHCOMPLIANCE@kent.edu. Be sure to include "clean", unstamped copies of the consent form, scripts, etc...

   To submit the form with a typed signature, the form must be submitted from the Investigator's @kent.edu email account. If completed form is signed and then scanned as a PDF attachment, the @kent.edu email requirement does not apply.

IRB Office use only

Date Received	**4/27/21**
Name of Discipline Specific Reviewer	
Agenda Date	**August 2021**
Date of IRB Determination email to Investigator	
IRB ACTION	**Date**
☐ Approved (CR)	**5/23/21-5/22/22 (2)**
☒ Approved (AR)	
☐ Other	
STAMP CONSENT ☒ Yes ☐ No	EXTERNAL FUNDING ☐ Yes ☒ No

_____
Signature of Chair, IRB Date

_____
Signature of IRB Administrator or Designee Date

TO COMPLETE THIS FORM: ***SINGLE LEFT-CLICK TO COMPLETE TEXT FIELDS. TO CHECK A BOX, DOUBLE LEFT-CLICK ON THE BOX, THEN CLICK "CHECKED". CLICK OK.***

Can your study be closed?

If all research-related interventions and/or interactions with participants have been completed and data is de-identified, do not submit this form - you must file a closeout form

Section 1 - KSU Investigator Information

Last Name: Lechner First Name: Ahmad IRB Log Number: 18-199

Title of Study (should match Human Subjects Research Application):

Examining alcohol consumption, perceptions, and user experience of alcohol moderation strategies.

Section 2 - RESEARCH STATUS

a. Indicate the status of the research:

☐ Research participants have NOT been enrolled (or participant records, specimens, etc.

obtained).

Explain: _____

☒ Research participants HAVE been enrolled (or participant records, specimens, etc. obtained)

b. If participants have been enrolled,

☒ Recruitment is ongoing

☐ Recruitment has been completed → Check **all** that apply

☐	1.	Interactions and/or interventions are continuing.
☐	2.	All research related interaction and intervention have been completed **or** the research did not involve interaction/interventions.
☐	3.	Data contains identifiers.
☐	4.	Data is de-identified.

If you selected options 2 and 4 you need to submit a closeout form. Do not submit this form.

Section 3 INVESTIGATOR INFORMATION

CO-INVESTIGATOR(S) & KEY PERSONNEL (Kent State University personnel only)

a. Are key personnel being added to the study? ☐ Yes ☒ No

If Yes → Please List:

b. Are key personnel being removed from the study? ☐ Yes ☒ No

If Yes →Please list:

"Key personnel" are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals, who recruit participants, obtain consent or, who collect study data. You must submit CITI certificates for new personnel.

Are the human subjects protection online training requirements (CITI) current for all Kent State investigator(s) and key personnel? ☒ Yes ☐ No

Section 4 - EXTERNAL CO-INVESTIGATOR(S) & KEY PERSONNEL (non-Kent State University personnel only)

Are there any changes in external study personnel? ☐ Yes →Complete Appendix B ☒ No

KENT STATE UNIVERSITY

Section 5 - FINANCIAL CONFLICT OF INTEREST

a. Does any Kent State University investigator (including principal or co-investigator), key personnel, or their immediate family members have a financial interest (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?	☐ Yes ☒ No

Section 6 - FUNDING OR OTHER SUPPORT

If the research is externally funded and/or involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact the Office of Research Compliance for more information.

a. What is the current funding status of the research?	☒ None ☐ Funded
If funded → Specify sponsor	
If funded→ Does the sponsor require annual review?	☐ Yes ☐ No
b. Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?	☐ Yes ☐ No
If Yes → Specify support and provider:	

KENT STATE UNIVERSITY

Section 7 - RESEARCH SUMMARY

Summarize the research made using ***non-technical*** language that can be readily understood by someone outside the discipline. Explain briefly the research design, procedures used, risks and anticipated benefits, and the importance of the knowledge that may be expected to result. ***Use complete sentences (limit 500 words).***

Heavy episodic drinking is related to a range of unfavorable outcomes and represents a significant public health problem. Despite experiencing significant negative consequences, the majority of problem drinkers will never seek treatment from a direct care provider (SAMHSA, 2015). Mobile technology has the potential to transform how alcohol interventions are delivered by providing a more direct platform to promote behavior change. Indeed, mobile technologies have demonstrated utility in providing treatment information for a wide-range of behaviors for which individuals often hesitate to seek professional help, including smoking cessation, sexual health, weight management, and anxiety (Cohn, Hunter-Reel, Hagman, & Mitchell, 2011). Moreover, recent research suggests that tools aimed at reducing irresponsible drinking behaviors often fail because they do not account for barriers to treatment implementation caused by the intoxicating effects of alcohol. Alcohol directly affects several underlying neurocognitive mechanisms necessary for adhering to drinking limits (Day et al., 2015; Guillot, Fanning, Bullock, McCloskey, & Berman, 2010; Kahler et al., 2014; Lechner, 2016). Specifically, alcohol affects the ability to maintain focus on previously defined goals (e.g. I will only have 2 drinks), and to weigh those goals against competing acute reinforcers (pleasurable effects of alcohol) (Houben, Wiers, & Jansen, 2011). Therefore, two major barriers to changing problematic patterns of alcohol use include (1) willingness to seek professional help despite motivation to change, (2) difficulty adhering to pre-defined drinking limits caused by alcohol's intoxicating effects. The current application proposes to test a mobile application with potential to address both of these barriers. First, the mobile application provides an active self-help based platform for moderating alcohol use that is accessible without seeking assistance from a health-care provider. Second, the application provides guidance on moderating alcohol use in real time based on individual users pre-defined drinking limits, which helps reduce demands on the neurocognitive mechanisms that are diminished following alcohol consumption. Specifically, the application utilizes an algebraic formula to proactively pace a user's alcohol consumption over time (provides a visual cue of how much of their current beverage should be remaining, as well as the time remaining until they can start their next drink) based on their predefined drinking limits, as well as individual factors including weight, sex, and other variables affecting the metabolism of alcohol.

Section 8 - RECRUITMENT & INFORMED CONSENT PROCESS

a. Were recruitment materials used to enroll participants?

☒ Yes
☐ No

If Yes → Are recruitment materials still being used?

☒ Yes → ***Provide copies of the current recruitment materials (ads, radio/TV scripts, internet solicitations, etc.).***
☐ No

b. How **was/is** informed consent or assent obtained? Check all that apply. ***Provide "clean" copies of all current documents***.

☐ Assent – Form
☐ Assent – Verbal Script
☐ Parental Permission – Form
☐ Parental Permission – Verbal Script

KENT STATE UNIVERSITY

- ☒ Informed Consent – Form
- ☒ Informed Consent – Verbal Script
- ☐ Informed Consent – Addendum
- ☐ Translated Consent/Assent – Form(s)
- ☐ Waiver or Alteration of Consent Process
- ☐ Waiver of Consent Documentation

c. Is deception of participants part of the research?

- ☐ Yes → ***Provide copy of current debriefing script or other information sheet(s) used to inform participants.***
- ☒ No

Section 9 - RESEARCH PROGRESS

A. Summarize the progress of the research, including any interim findings.

To date, we have consented 34 participants. Recruitment was significantly slowed due to COVID-19 study suspensions and time needed to ensure study procedures conformed to research activity requirements introduced due to the COVID-19 pandemic.

B. For multi-site studies, summarize the overall progress of the research. *Attach a copy of the most recent multi-site study report, if any.* ☒ N/A

C. Summarize any IRB-approved amendments or changes made to the research since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation. ☐ N/A

Approved Amendment 3/4/21

We requested approval to screen potential participants via electronic survey. No additional assessments were added, we modified our phone screen to screen participants via Qualtrics survey platform.

Approved Amendment 1/13/21

We requested changes to our recruitment materials to include Facebook/Instagram advertising. This change was done to improve recruitment efforts following COVID-19 lockdown restrictions.

D. Summarize recent literature or other new information relevant to the research, if any, since last IRB review (initial or continuing). ☒ N/A

E. Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could affect participants' willingness to continue in the research and how participants have been or will be informed. ☒ N/A

F. Indicate projected or actual completion date (month and year): *Indicate "ongoing" for repository research or program protocols* **5/1/2022**

KENT STATE UNIVERSITY

Section 10- NUMBER OF PARTICIPANTS

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

a. Is this a multi-site study?

☐ Yes → Indicate the total number of participants to be enrolled across all sites:

☒ No

b. For research approved by an Kent State University IRB, provide:

1) IRB approved number of participants (or records, specimens, etc.): **64**

2) Total number of participants enrolled in the research to date: **34**

3) Number of participants enrolled since last IRB review (initial or continuing): **4**

c. If the actual total enrollment to date is significantly different (over or under) from IRB approved number, provide an explanation:

Recruitment is lower than originally projected due to COVID-19 related study suspensions.

d. Are you requesting an increase in the total number of participants?

☐ Yes → **answer a & b**

☒ No

a. What is the requested number of participants (or records, specimens) to be added?

b. Provide rationale for adding participants:

Section 11 - PARTICIPANT COMPLAINTS & VOLUNTARY WITHDRAWALS

a. Have any participants made complaints about the research since the last IRB review?

☐ Yes

☒ No

If Yes → **List and describe each complaint and any actions taken to resolve the complaint(s).**

b. Have any participants voluntarily withdrawn from the research since last IRB review? *Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.*

☐ Yes

☒ No

If Yes → **List and describe each withdrawal and any actions taken (e.g., changes to the research or consent process) in response to the withdrawal(s).**

Section 12 - RISK ASSESSMENT

a. Since the last IRB review (initial or continuing), did any unanticipated problems involving risks to subjects or others or adverse events occurred in research?

☐ Yes → Complete Appendix R

☒ No

b. Is the research subject to Data and Safety Monitoring Board (DSMB) or other similar committee/group review?

☐ Yes → ***Provide a copy of the most current report.***

☒ No

c. Provide an assessment of the risks and potential benefits *based on study results* since last IRB review.

The risks and potential benefits have not changed since the last IRB review.

d. Summarize recent literature or other new information relevant to the research, if any, since last IRB review (initial or continuing). ☒ N/A

e. Discuss significant new findings (e.g., affecting risks, benefits, or alternatives), if any, that could affect participants' willingness to continue in the research and how participants have been or will be informed. ☒ N/A

Section 13 - PRINCIPAL INVESTIGATOR'S ASSURANCE

I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Continuing/Annual Review form is accurate and complete.

W. V. Lechner — **4/27/2021**

Signature of Principal Investigator — Date

William Lechner

Printed name of Principal Investigator

Informed Consent to Participate in a Research Study

Study Title: Examining alcohol consumption, perceptions, and user experience of alcohol moderation strategies.

Principal Investigator: William Lechner, Ph.D.

You are being invited to participate in a research study. This consent form will provide you with information on the research project, what you will need to do, and the associated risks and benefits of the research. Your participation is voluntary. Please read this form carefully. It is important that you ask questions and fully understand the research in order to make an informed decision. You will receive a copy of this document to take with you.

Purpose

We are interested in testing the usability of a alcohol moderation strategies aimed at helping users drink within limits that they set for themselves before drinking.

Procedures

We will ask you to complete a battery of measures including questions about demographics, measures related to alcohol use, psychological / psychiatric measures such as questions about symptoms of anxiety or depression; and neuropsychological and behavioral economic tasks that measure your cognitive performance and preference for short and long term rewards. Then, we will ask you to utilize alcohol moderation strategies during the two-week observation period. Lastly, we will ask you to complete the same battery of measures once again after the two-week observation period.

In order to participate in this task, you must have a smartphone and be willing to download a mobile application. All study procedures are completely confidential. The study will consist of one laboratory visit which will take 2 hours to complete and one online follow-up session which will take 2 hours to complete, resulting in 4 hours of participation in total. Participation also consists of a two-week observation period during which you may be asked to use a mobile application accessible via smartphone. If you are asked to utilize this application you will also be required to sign and agree to the End User License Agreement associated with the application which includes agreement to use the application as an estimate of the alcohol effects and to use alcohol (if you choose) in accordance with all state and federal laws.

Benefits

There are no direct benefits to you for participating in this study. You will have a chance to contribute to a scientific study that may help people in the future.

Risks and Discomforts

Emotional discomfort may be associated with completing the assessments and questionnaires. The questionnaires used in this study have been used in other similar research studies. Some of the questions may be of an embarrassing or sensitive nature and may make you uncomfortable. Therefore, you are free not to answer any questions you do not wish to answer. The time spent completing this study may represent an inconvenience. Additionally, the current study may require that you download and utilize a mobile application; this application will collect data on the time and location you are in when you use the application, your internet protocol (IP) number, and information you enter into the data fields. Upon completion, users may close the app, concluding data collection. There is no guarantee that the use of this app will prevent intoxication, the purpose of this app is to assist individuals seeking moderation in drinking habits. The use of this app may result in alcohol intoxication which may lead to potential harm.

IMPORTANT: PLEASE READ THIS LICENSE CAREFULLY AND INITIAL BEFORE USING THIS SOFTWARE .

1. **LICENSE.**

1.1 **Legally Binding Agreement.** By installing and/or using the Social Drinker mobile device application (hereinafter the "Software"), you agree this End User License Agreement (hereinafter, the "Agreement") is a legally binding and valid contract and agree to be bound by all of the terms and conditions contained herein. Specifically, but without any limitation you agree to indemnify, release and hold Even Moderation, LLC as the owner with all rights and privileges to the Software (the "Company), and all of its officers, managers, employees, agents or distributors from any and all liability as more fully described and agreed to herein.

1.2 **Use and Rights Limited by Agreement.** Subject to the terms of this Agreement, the Company grants you a limited, non-exclusive, non-transferable license, without right to sub-license, to use the Software in accordance with this Agreement. The Company does not transfer the title of "Social Drinker" to you and the license granted to you is not a sale. This Agreement is a binding legal agreement between the Company and the purchasers and users of the Software. If you do not agree to be bound by this Agreement, you agree to and shall immediately cease use of the Software and immediately remove the Software from any and all electronic and/or mobile devices owned or controlled by you.

_____ _____

Participant Initials **Date**

2. **DISTRIBUTION.**

2.1 **No Right to Distribute.** The Software and license granted herein shall not be copied, shared, distributed, re-sold, offered for re-sale, transferred or sub-licensed in whole or in part.

Participant Initials **Date**

3. USER AGREEMENT.

3.1 **Use of Software.** Use of the Software is limited to the number of licenses purchased by you. A single purchase of this Software shall grant you one (1) license to be used on a single electronic and/or mobile device.

3.2 **Restrictions.** You shall use Social Drinker in compliance with any state, local or federal law or regulation of the United States or any law or regulation of any applicable foreign jurisdiction.

3.3 **Copyright Restriction.** This Software contains copyrighted material, trade secrets and other proprietary material. You shall not, and shall not attempt to, modify, reverse engineer, disassemble or decompile the Software. You shall not create any derivative works or other works that are based upon or derived from the Software in whole or in part.

(a) You agree that you shall not use the Company's name, logo or any graphics associated therewith that represent the Software in any way or manner whatsoever. The Company retains sole and exclusive ownership of all rights, title and interest in and to the Software and all intellectual property rights relating thereto.

(b) Copyright law and international copyright treaty provisions protect all parts of the Software. No program, code, part, image, audio sample, or text may be copied or used in any way by the user except as intended within the bounds of the ordinary and necessary use of the Software. All rights not expressly granted hereunder are reserved for the Company.

Participant Initials **Date**

4. RESPONSIBLE USE

4.1 **Estimates Only.** The Software provides an estimate of a user's blood alcohol content ("BAC") only, and you agree that you shall not rely in any way upon the estimate of BAC provided by the Software. You agree that you shall not rely upon the Software in any way to comply with any alcohol consumption, alcohol impairment driving statute, or any other applicable law or regulation of any jurisdiction whatsoever, including that of any state, local or federal law or regulation of the United States or any applicable law or regulation of a foreign jurisdiction.

4.2 **No Reliance Upon Estimated Calculations.** The information displayed, provided and/or generated by, including any user interaction with the Software, including any text, graphics, images and other material provided are estimates and are not to be otherwise relied upon by the user ("Content"). The Content is

not intended to be a substitute for professional medical advice, diagnosis, or treatment. You specifically acknowledge and agree to the following: standard alcoholic drinks of every variety vary in size and alcohol content, individual alcohol absorption and elimination rates fluctuate, and your actual BAC will differ from the result of any calculated estimate of BAC set forth by the Software.

4.3 **No Medical Advice.** The Software does not provide medical advice. Always seek the advice of your physician or other qualified health provider with any questions you may have regarding a medical ailment, condition, or substance dependency issue. Never disregard professional medical advice or delay in seeking a professional opinion because of your use of the Software.

4.4 **Responsible Use.** You agree the Software shall only be used in a responsible manner and not as part of any competition or contest whatsoever.

_____ _____

Participant Initials **Date**

5. DISCLAIMER OF WARRANTY

5.1 **NO WARRANTIES.** TO THE FULLEST EXTENT POSSIBLE BY LAW, THE COMPANY DOES NOT WARRANT THAT THE SOFTWARE WILL OPERATE ERROR-FREE OR THAT THE SOFTWARE IS FREE OF, OR IN ANY WAY SUSCEPTIBLE TO A COMPUTER VIRUS OR OTHER HARMFUL MECHANISMS. IF YOUR USE OF THE SOFTWARE RESULTS IN THE NEED FOR SERVICING OR REPLACING EQUIPMENT OR DATA OR ANY OTHER COSTS, THE COMPANY IS NOT RESPONSIBLE FOR THOSE COSTS. THE SOFTWARE IS PROVIDED "AS IS" WITHOUT ANY WARRANTIES OF ANY KIND. THE COMPANY, TO THE FULLEST EXTENT PERMITTED BY LAW, DISCLAIMS ALL WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING THE WARRANTY OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE, AND NON-INFRINGEMENT. THE COMPANY MAKES NO WARRANTIES ABOUT THE ACCURACY, RELIABILITY, AND COMPLETENESS OR TIMELINESS OF THE CONTENT PROVIDED BY THE SOFTWARE.

_____ _____

Participant Initials **Date**

6. CONSENT OF USE OF DATA

6.1 **Consent of Data Collection.** You agree the Company may collect and use information gathered in any manner by the Software and has the full right, permission and authorization to utilize such information for any research, scientific or commercial purpose whatsoever, including the release, utilization and/or sale of such information to a third-party or as part of any product support services provided to you. The Company may use any information compiled by the Software to periodically provide notice or information to you, including, but not limited to any third-party advertisements.

_____ _____

Participant Initials **Date**

7. MISCELLANEOUS

7.1 **Indemnification.** You will indemnify, release, hold harmless, and pay all costs associated with a legal defense of the Company, its officers, managers, employees, agents and distributors against any and all claims, proceedings, demands, or costs, including, but not limited to that arising from any and all injury, liability or claim of injury to or death of any person or for loss of or damage to property, resulting from or in any way connected, directly or indirectly with use of the Software.

7.2 **Release of Damages.** In no event (including, without limitation, in the event of negligence) will the Company, its officers, managers, employees, agents or distributors be liable for any consequential, incidental, indirect, special or punitive damages whatsoever (including, without limitation, damages for loss of profits, loss of use, business interruption, loss of information or data, or pecuniary loss), in connection with or arising out of or related to this Agreement, the Software or the use or inability to use the Software or the furnishing, performance or use of any other matters hereunder whether based upon contract, tort or any other theory including negligence.

7.3 **Governing Law.** This Agreement shall be governed by and interpreted and enforced in accordance with the substantive laws of the State of Pennsylvania (including, without limitation, provisions concerning limitations of actions), without reference to the conflicts of laws rules of that or any other jurisdiction, except that Federal laws shall also apply to the extent relevant.

7.4 **Consent to Jurisdiction.** You hereby (i) irrevocably submit to the jurisdiction of the Court of Common Pleas in Erie County or the U.S. District Court for the Western District in any action arising out of this Agreement, (ii) agree that all claims in such action may be decided in such court, (iii) waives, to the fullest extent it may effectively do so, the defense of an inconvenient forum, and (iv) consents to the service of process by mail. A final judgment in any such action shall be conclusive and may be enforced in other jurisdictions.

7.5 **Severability**. If any provision of this Agreement or the application thereof to any person or circumstance is held invalid or unenforceable to any extent, the remainder of this Agreement and the application

of that provision to any other persons or circumstance shall not be affected thereby and that provision shall be enforced to the greatest extent permitted by law.

7.6 **Termination.** Any failure to comply with the terms and conditions of this Agreement will result in automatic and immediate termination of this license. Upon termination of this license granted herein for any reason, you agree to immediately cease use of the Software and destroy all copies of the Software supplied under this Agreement.

_____ _____

Participant Initials **Date**

Alternatives

You may check the list of SONA studies and find an alternative study that you can complete that provides the course credit required for you.

Privacy and Confidentiality

Identifying information will not be included in the data that you provide. Your study related information will be kept confidential within the limits of the law. Any identifying information will be kept in a secure location and only the researchers will have access to the data. Research participants will not be identified in any publication or presentation of research results; only aggregate data will be used. Your research information may, in certain circumstances, be disclosed to the Institutional Review Board (IRB), which oversees research at Kent State University, or to certain federal agencies. Confidentiality may not be maintained if you indicate that you may do harm to yourself or others.

Compensation

You will be compensated $40 for the baseline laboratory session and $40 for the online follow-up session for a total of $80 for completing the study.

Voluntary Participation

Taking part in this research study is entirely up to you. You may choose not to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you are otherwise entitled. You will be informed of any new, relevant information that may affect your health, welfare, or willingness to continue your study participation.

Contact Information

If you have any questions or concerns about this research, you may contact William Lechner at wlechner@kent.edu or (330) 672-3786. This project has been approved by the Kent State University

Institutional Review Board. If you have any questions about your rights as a research participant or complaints about the research, you may call the IRB at 330.672.2704.

Consent Statement and Signature

I have read this consent form and have had the opportunity to have my questions answered to my satisfaction. I voluntarily agree to participate in this study. I understand that a copy of this consent will be provided to me for future reference.

_____ _____

Participant Signature **Date**

VERBAL CONSENT TO ACT AS A RESEARCH SUBJECT

Examining Alcohol Consumption, Perceptions, and User Experience of Alcohol Moderation Strategies

Dr. William Lechner and his associates are interested in testing the usability of alcohol moderation strategies aimed and helping users drink within limits that they set for themselves before drinking.

The purpose of this screening is to determine your eligibility for the research study and will take approximately 5 minutes. If you agree to participate in this screening, you will be asked some questions regarding your substance use. If you are eligible, we will schedule the main study session including the informed consent process, a clinical interview, questionnaires, and computer tasks at KSU, which will take about 2 hours. Then, we will ask you to utilize and monitor your use of alcohol moderation strategies for two weeks. Lastly, we will ask you to complete an online follow-up survey after the two-week period. The entire study will take up to 4 hours to complete, and you can earn $80 for your participation.

Participation in this phone screen may involve some added risks or discomforts. Being asked questions related to substance use may cause anxiety or embarrassment due to the personal nature of the questions. You may decline to answer any item. If you experience any anxiety or embarrassment, you have the option to discuss this with Dr. William Lechner, the primary investigator of this study.

Your responses to this phone screen will be recorded on a form identified by an ID number and does not include your name or other identifying information. If you are ineligible for the study, the form on which I record your responses will be destroyed immediately. If you are eligible and decide to take part in the study, your recorded responses will be securely stored, separated from any identifying information.

Do you have any questions about this phone screen? If you have other questions, you may reach Dr. Lechner at (330) 672-2027 for more information about this study.

Participation in this telephone screen is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled.

Research records will be kept confidential. Do you agree to participate? YES / NO

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Verbal Consent Date

Research participants wanted for a study assessing strategies to control drinking.

Participants must:

- ☐ Be 21 years or older
- ☐ Drink alcohol regularly
- ☐ Own a smart phone

In this study we will ask you to complete a two hour session at Kent State University that includes questions related to alcohol use, symptoms of anxiety or depression, and neuropsychological tasks that measure your cognitive performance. At the end of this session we will explain techniques for controlling or limiting your drinking – if you choose to do so. Then we will ask you to monitor your drinking (how many drinks per day you have) for a two-week period. Finally, we will send you a link to complete outcome measures asking the same questions you completed in the laboratory session – this will take about two hours to complete. All sessions are completely confidential.

Compensation: Participants will be compensated $40 for completing the first 2-hour session at Kent State and an additional $40 for completing the final assessment online - $80 in total.

If you are interested, please contact study personnel via email or phone:

Lechnerlab@gmail.com

(330) 672-2027

IRB LOG NUMBER: 16-

Use of Human Subjects in Research Application

(LEVEL II or LEVEL III projects)

THIS SECTION FOR USE BY IRB	Date received by ORC	
Name of discipline -specific reviewer: Dr. Doug Delahanty		
Level of review (please choose either Expedited or Full board)		
☐ **Level II – Expedited Review** *Please specify one or more category:* ☐ - #1 - Clinical Studies ☐ - #2 - Collection of Blood Samples ☐ - #3 - Pros collection of Bio Specimens ☐ - #4 - Data through non-invasive procedures. ☐ - #5 - Materials (Data, documents, records or specimens collected for non-research purposes) ☐- #6 - Data from voice, video, digital or image recordings ☐- #7 - Individual or group characteristics	☒ **Level III – Full Board Review** Agenda Date: Notes:	

INSTRUCTIONS FOR INVESTIGATORS:

1. Submit this completed document with any needed attachments via email attachment to an IRB discipline specific reviewer.

This form must be submitted from the Principal Investigator's @kent.edu email account.

Submission of incomplete forms or failure to include all of the needed attachments will likely result in delays for IRB review/approval. Handwritten forms are not accepted.

Single left-click to complete text fields.

To check a box, double left-click on the box, then click "checked". Click OK.

2. Do NOT begin data collection prior to receiving notification from the KSU IRB that the study has received final approval.

Section 1 – TITLE & PRINCIPAL INVESTIGATOR (PI) INFORMATION

1a. Title of Study: Examining alcohol consumption, perceptions, and user experience of alcohol moderation strategies.

1b. Estimated begin and end dates for the project		4/2018 to 4/2019
1c. Name: **William Lechner**		Status: ☒ Faculty ☐ Staff
1d. Phone: (814) - 450 - 1093 or extension		Department: Psychological Sciences
1e. Purpose of Research	☒ Faculty Research ☐ Student Thesis/Dissertation ☐Complete Appendix A ☐ Other: Specify:	PI Email: wlechner @kent.edu

Only faculty members and professional staff who are full-time university employees are eligible for PI status. Students conducting research for their dissertation or master's thesis research can still have primary responsibility for the intellectual content, conduct of the research, or primary authorship in publications by serving as co-investigators or key personnel on IRB applications. If you are a KSU employee conducting research involving human subjects as part of your graduate or undergraduate program, your faculty advisor must serve as the PI of record for IRB protocols. Please review IRB policy for PI eligibility and responsibilities.

1f. Please provide keywords that best describe your research: alcohol moderation, mobile technology

1g. Email address(es) for others that should be notified regarding the status of this application (i.e., student(s) conducting research, program administrators, etc.):	wlechner @kent.edu

1h. Are there any Kent State University affiliated co-investigators or key personnel on this protocol?

"Key personnel" are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals, who recruit participants, obtain consent or, who collect study data. Students conducting research for their dissertation or master's thesis research can still have primary responsibility for the intellectual content, conduct of the research, or primary authorship in publications by serving as co-investigators or key personnel on IRB applications.

☐ Yes Complete Appendix A

☒ No

1i. Are there any external (non-Kent State University affiliated) co-investigators or key personnel *engaged* in the research?

"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Kent State University. See OHRP Engagement Guidance or contact ORC for more information.

☐ Yes Complete Appendix B

☒ No

1j. Has the Principal Investigator (PI) I completed the required web-based course years (CITI, or equivalent) in the protection of human research subjects?

Educational requirements (initial and continuing) should be satisfied prior to submitting the application for IRB review. See Human Subjects Protection Training policy for more information. Final approval from the IRB will not be obtained until all requirements are fulfilled.

☐ Yes Attach

☐ No

1k. Is this protocol a continuation of or linked to a previously reviewed IRB protocol?

If Yes Please list the protocol number(s)

☐ Yes

☒ No

Section 2 – FUNDING INFORMATION

2a. Does this research have external or internal funding, or have you requested funding for this research?

☐ Yes
☒ No

If Yes ▯ Specify sponsor:

Protocol/Proposal # Institution (if not KSU):

If No ▯ Please provide a short description of barriers to applying for, or receiving funding so that our Division can try to help you in future efforts...
This is a preliminary study to examine usability of the mobile application.

2b. Have you created an account and search for research funding opportunities at Pivot.cos.com?
Please contact the Research Division if you would like more information or assistance with PIVOT.

☐ Yes
☒ No

2c. Is any support other than monetary (e.g., drugs, equipment, supplies, etc.) being provided for the study?

☐ Yes
☐ No

If Yes ▯ Specify support and provider:
Attach a copy of the grant application or funding proposal.

The university is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded. If the research funded by a federal agency and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. Contact the Office of Research Compliance (ORC) for more information.

2d. Does the PI for this research or their immediate family members *(i.e, spouse, domestic partner, or dependent children*) have a financial interest that would reasonably be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research?
Financial interests include (but are not limited to) salary or other payments for services (e.g., consulting fees or honoraria), equity interests (e.g., stocks, stock options, or other ownership interests), and intellectual property rights (e.g., patents, copyrights, and royalties from such rights).

☐ Yes ▯Complete Appendix Z
☒ No

2e. Does the PI for this research or their immediate family members *(i.e, spouse, domestic partner, or dependent children*) have a non-financial Conflict of Interest that would reasonably be affected by the research?
A non-financial conflict of interest is an interest, other than monetary, of an individual (or his/her immediate family) in the design, conduct, or reporting of the research or other interest that competes with the obligation to protect research participants and potentially compromises the objectivity and credibility of the research process.

☐ Yes ▯Complete Appendix Z
☒ No

Section 3 – RESEARCH DESIGN

3a. Will research activities be conducted at a site where approval from an additional IRB (other than KSU IRB) is needed?

In some cases research conducted at locations other than Kent State University (i.e., other universities, hospitals, prisons) may require another institution's IRB approval, a letter of support (as in the case of elementary or high schools), or the execution of an IRB

☐ Yes ▯ Complete Appendix O
☒No

46.114 Cooperative Research

Authorization or Individual Investigator Agreement. See OHRP Engagement Guidance or contact ORC for more information.

3a. Is any of this research being conducted outside of the U.S.A? ☐ Yes ☐ Complete Appendix U ☒ No

3b. Briefly summarize the purpose of the proposed research using ***non-technical*** language that can be readily understood by someone outside the discipline. ***Use complete sentences (limit 500 words).***

Heavy episodic drinking is related to a range of unfavorable outcomes and represents a significant public health problem. Despite experiencing significant negative consequences, the majority of problem drinkers will never seek treatment from a direct care provider (SAMHSA, 2015). Mobile technology has the potential to transform how alcohol interventions are delivered by providing a more direct platform to promote behavior change. Indeed, mobile technologies have demonstrated utility in providing treatment information for a wide-range of behaviors for which individuals often hesitate to seek professional help, including smoking cessation, sexual health, weight management, and anxiety (Cohn, Hunter-Reel, Hagman, & Mitchell, 2011). Moreover, recent research suggests that tools aimed at reducing irresponsible drinking behaviors often fail because they do not account for barriers to treatment implementation caused by the intoxicating effects of alcohol. Alcohol directly affects several underlying neurocognitive mechanisms necessary for adhering to drinking limits (Day et al., 2015; Guillot, Fanning, Bullock, McCloskey, & Berman, 2010; Kahler et al., 2014; Lechner, 2016). Specifically, alcohol affects the ability to maintain focus on previously defined goals (e.g. I will only have 2 drinks), and to weigh those goals against competing acute reinforcers (pleasurable effects of alcohol) (Houben, Wiers, & Jansen, 2011). Therefore, two major barriers to changing problematic patterns of alcohol use include (1) willingness to seek professional help despite motivation to change, (2) difficulty adhering to pre-defined drinking limits caused by alcohol's intoxicating effects. The current application proposes to test a mobile application with potential to address both of these barriers. First, the mobile application provides an active self-help based platform for moderating alcohol use that is accessible without seeking assistance from a health-care provider. Second, the application provides guidance on moderating alcohol use in real time based on individual users pre-defined drinking limits, which helps reduce demands on the neurocognitive mechanisms that are diminished following alcohol consumption. Specifically, the application utilizes an algebraic formula to proactively pace a user's alcohol consumption over time (provides a visual cue of how much of their current beverage should be remaining, as well as the time remaining until they can start their next drink) based on their predefined drinking limits, as well as individual factors including weight, sex, and other variables affecting the metabolism of alcohol.

3c. List the scientific or scholarly aims of the research study

The main objective of the current study is to obtain information regarding user experience, overall design, and willingness to use the mobile application in a sample of young adults reporting at least one negative consequence of alcohol use in the past month and endorsing some interest in changing drinking behaviors. A secondary objective of the current study is to examine the initial efficacy of the proposed mobile intervention in reducing negative consequences of alcohol use and to examine correlates of any change (e.g. symptoms of anxiety, drinking motives, executive function).

3d. Summarize existing knowledge and previous work that support the expectation of obtaining useful results without undue risk to human subjects. ***Use complete sentences (limit 300 words).***

In general, mobile technologies have been shown to be useful in providing treatment information for a wide-range of health related behaviors for which individuals often fail to seek professional help (Cohn, Hunter-Reel, Hagman, & Mitchell, 2011). Systematic reviews suggest that mobile digital interventions can reduce alcohol use in adults (Fowler, Holt, & Joshi, 2016). Preliminary evidence suggests that non treatment-seeking young adults will engage with a mobile text message intervention incorporating self-regulation support features, and that depending on level of engagement users may meet their drinking goals – suggesting promise for mobile based alcohol reduction interventions (Suffoletto, Chung, Muench, Monti, & Clark, 2018). However, questions regarding the mechanisms, reliability, and magnitude of these effects remain unanswered.

3e. Identify and describe the interventions and interactions that are to be performed solely for the research study. *Procedures/interventions should listed sequentially and be separated into paragraphs in the space below.*

Participants will be recruited using the Kent State University SONA system and from the community via flyers and online advertisement. Eligible participants will meet the following inclusion criteria 1) be age 21 or older, 2) report experiencing at least three negative consequence of alcohol use in the past month (assessed via Brief Young Adult Alcohol Consequences Questionnaire: BYAACQ), 3) report having consumed at least 5 drinks (for men) or 4 drinks (for women) on one or more occasions in the past 2-weeks 4) not be seeking treatment for alcohol use from a health-care provider, and 5) have access to a smartphone and 6) endorse some importance in changing their drinking (2 or greater on Alcohol Ladder Scale importance to change). Participants who endorse seeking treatment for alcohol related problems from a health care provider will be provided with a list of university sponsored and community based treatment providers.

Participants (n=64) will complete a battery of assessments detailed below including (1) demographic measures, (2) alcohol and substance use measures, (3) psychological measures, (4) behavioral economic and (5) neuropsychological measures.

(1) Demographic Measures: will include brief questions about demographic characteristics biological sex, race, and socio-economic status.

(2) Alcohol and Other Substance Use: The Timeline Follow-back Interview will be used to assess alcohol use over the prior 30 days[1]. The Implicit Association Test is a reaction time task requiring participants to manipulate alcohol related stimuli and has been shown to be a reliable measure of automatic impulses to drink alcohol [2, 3]. The Young Adult Alcohol Consequences Questionnaire (YAACQ) will be used to assess a range of negative consequences of alcohol use that young adults may experience (e.g., while drinking in the past month, I have said or done embarrassing things). Assessment of Diagnostic and Statistical Manual of Psychiatric Disorders V (DSM-V)[4] alcohol related symptoms (e.g. During the times when you drank alcohol, did you end up drinking more than you planned when you started?). The Drinking Motive Questionnaire Revised Short Form (DMQ–R SF): assesses motives for drinking in adolescents and young adults in four categories (social, coping, enhancement, social pressure)[5]. The Alcohol Expectancies Brief[6] measures positive and negative expectancies of alcohol use. Alcohol Contemplation Ladder is a measure of importance and motivation to make a change in one's alcohol consumption[7]. Smoking History/Dependence Questionnaire: Smoking history and life smoking patterns will be assessed as recommended by the National Cancer Institute consensus panel (e.g. have you ever used tobacco products; how often do you use tobacco products). The Self-Report Habit Index (SRHI) measures adult habitual substance use . Additional questions regarding substance use history (specifically pertaining to age of onset and frequency of use for various illicit/unregulated substances) will also be administered.

(3-5) Neuropsychological, Behavioral Economic, and Psychological Measures: Working Memory Performance and Inhibition will be measured using the National Institute of Health Examiner (Executive Abilities) [8]. The Monetary Choice Questionnaire (Delay Discounting) is a behavioral economic measure for assessing state in subjective value of delayed rewards, with greater discounting of value indicative of decreased self-control[9, 10]. Psychological Measures: will include The UPPS-P Impulsive Behavior Scale: a self-report that assesses five subscales that are used to measure distinct dimensions of impulsive behavior[11]. The Difficulties in Emotional Regulation Scale (DERS) will be used to measure the ability to utilize several emotion regulation strategies. The Positive and Negative Affect Scale will be administered to measure changes in affect[12]. Symptoms of depression, anhedonia, and anxiety will be assessed using the Center for Epidemiologic Studies –Depression Scale (CES-D)[13], SHAPS Anhedonia scale[14], and Generalized Anxiety Disorder 7-item (GAD-7)[15].

Following this initial baseline assessment, participants will be randomized to one of two experimental conditions detailed below. If they are randomized to Alcohol Moderation Group 1 they will receive a link to access the Alcohol Moderation software via smartphone, and a brief demonstration on how to utilize the application will be provided by trained research assistants. Participants will be asked to use the application if they consume alcohol at any point during the two-week observation period. Participants will not be encouraged to use alcohol, and will be clearly informed that there will be no penalty for not using the application during a drinking session or not drinking at all during the two-week observation period.

Alcohol Moderation Group 1: Alcohol Moderation group 1 will be introduced to alcohol moderation strategies developed by the National Institute on Alcohol Abuse and Alcoholism. In addition to introducing participants to these drinking moderation strategies they will be asked to download and utilize the Social Drinker application, which addresses many of the strategies. A full description is listed below.

Small changes can make a big difference in reducing your chances of having alcohol-related problems. Whatever strategies you choose, give them a fair trial. If one approach doesn't work, try something else. But if you haven't made progress in cutting down after 2 to 3 months, consider quitting drinking altogether, seeking professional help, or both.

Here are some strategies to try, and you can add your own at the end. Identify perhaps two or three to try in the next week or two.

Keep track. *Keep track of how much you drink. Find a way that works for you: Carry a drinking tracker card in your wallet, make check marks on a kitchen calendar, or enter notes in a mobile phone notepad or personal digital assistant. Making note of each drink before you drink it may help you slow down when needed.*

Count and measure. *Know the standard drink sizes so you can count your drinks accurately. Measure drinks at home. Away from home, it can be hard to keep track, especially with mixed drinks, and at times, you may be getting more alcohol than you think. With wine, you may need to ask the host or server not to "top off" a partially filled glass.*

Set goals. *Decide how many days a week you want to drink and how many drinks you'll have on those days. It's a good idea to have some days when you don't drink. People who always stay within the low-risk limits when they drink have the lowest rates of alcohol-related problems.*

Pace and space. *When you do drink, pace yourself. Sip slowly. Have no more than one standard drink with alcohol per hour. Have "drink spacers"—make every other drink a non-alcoholic one, such as water, soda, or juice.*

Include food*. Don't drink on an empty stomach. Eat some food so the alcohol will be absorbed into your system more slowly.*

Find alternatives. *If drinking has occupied a lot of your time, then fill free time by developing new, healthy activities, hobbies, and relationships, or renewing ones you've missed. If you have counted on alcohol to be more comfortable in social situations, manage moods, or cope with problems, then seek other, healthy ways to deal with those areas of your life.*

Avoid "triggers." *What triggers your urge to drink? If certain people or places make you drink even when you don't want to, try to avoid them. If certain activities, times of day, or feelings trigger the urge, plan something else to do instead of drinking. If drinking at home is a problem, keep little or no alcohol there.*

Plan to handle urges. *When you cannot avoid a trigger and an urge hits, consider these options: Remind yourself of your reasons for changing (it can help to carry them in writing or store them in an electronic message you can access easily). Or talk things through with someone you trust. Or get involved with a healthy, distracting activity, such as physical exercise or a hobby that doesn't involve drinking. Or, instead of fighting the feeling, accept it and ride it out without giving in, knowing that it will soon crest like a wave and pass. Also, see the short module to help you handle urges to drink.*

Know your "no." *You're likely to be offered a drink at times when you don't want one. Have a polite, convincing "no, thanks" ready. The faster you can say no to these offers, the less likely you are to give in. If you hesitate, it allows you time to think of excuses to go along. Also, see the short module to help you build drink refusal skills.*

Many of these strategies are addressed within a mobile application we have developed. In this study we will ask you to utilize an application called Social Drinker to keep track of your drinking. The Social Drinker (http://socialdrinkerapp.com/) mobile application utilizes individually entered user information to monitor alcohol consumption and provide feedback for the pace of alcohol consumption in real time. The application works by reordering a standardized algebraic formula for calculating blood alcohol content. You will enter sex, weight, time since last meal, and alcohol consumption limits. You will be presented with a list of blood alcohol content (BAC) percentages accompanied with descriptions of the effects of these BAC levels on important cognitive functions including memory, coordination, and social adeptness. The program then uses these values to design a blood alcohol content curve which is used to pace your alcohol consumption over the period of time that you are consuming alcohol. Once the BAC curve is established you just wait to start your next drink until the program notifies you (a buzz in your pocket).

Alcohol Moderation Group 2:

Alcohol moderation Group 2 will be exposed to the National Institute of Alcohol Abuse and Alcoholism strategies for moderation, without access to the Social Drinker Application.

Small changes can make a big difference in reducing your chances of having alcohol-related problems. Whatever strategies you choose, give them a fair trial. If one approach doesn't work, try something else. But if you haven't made progress in cutting down after 2 to 3 months, consider quitting drinking altogether, seeking professional help, or both.

Here are some strategies to try, and you can add your own at the end. Identify perhaps two or three to try in the next week or two.

Keep track. *Keep track of how much you drink. Find a way that works for you: Carry a drinking tracker card in your wallet, make check marks on a kitchen calendar, or enter notes in a mobile phone notepad or personal digital assistant. Making note of each drink before you drink it may help you slow down when needed.*

Count and measure. *Know the standard drink sizes so you can count your drinks accurately. Measure drinks at home. Away from home, it can be hard to keep track, especially with mixed drinks, and at times, you may*

be getting more alcohol than you think. With wine, you may need to ask the host or server not to "top off" a partially filled glass.

Set goals. *Decide how many days a week you want to drink and how many drinks you'll have on those days. It's a good idea to have some days when you don't drink. People who always stay within the low-risk limits when they drink have the lowest rates of alcohol-related problems.*

Pace and space. *When you do drink, pace yourself. Sip slowly. Have no more than one standard drink with alcohol per hour. Have "drink spacers"—make every other drink a non-alcoholic one, such as water, soda, or juice.*

Include food*. Don't drink on an empty stomach. Eat some food so the alcohol will be absorbed into your system more slowly.*

Find alternatives. *If drinking has occupied a lot of your time, then fill free time by developing new, healthy activities, hobbies, and relationships, or renewing ones you've missed. If you have counted on alcohol to be more comfortable in social situations, manage moods, or cope with problems, then seek other, healthy ways to deal with those areas of your life.*

Avoid "triggers." *What triggers your urge to drink? If certain people or places make you drink even when you don't want to, try to avoid them. If certain activities, times of day, or feelings trigger the urge, plan something else to do instead of drinking. If drinking at home is a problem, keep little or no alcohol there.*

Plan to handle urges. *When you cannot avoid a trigger and an urge hits, consider these options: Remind yourself of your reasons for changing (it can help to carry them in writing or store them in an electronic message you can access easily). Or talk things through with someone you trust. Or get involved with a healthy, distracting activity, such as physical exercise or a hobby that doesn't involve drinking. Or, instead of fighting the feeling, accept it and ride it out without giving in, knowing that it will soon crest like a wave and pass. Also, see the short module to help you handle urges to drink.*

Know your "no." *You're likely to be offered a drink at times when you don't want one. Have a polite, convincing "no, thanks" ready. The faster you can say no to these offers, the less likely you are to give in. If you hesitate, it allows you time to think of excuses to go along. Also, see the short module to help you build drink refusal skills.*

Following the two week observation period participants will repeat baseline assessment procedures including: (2) alcohol and substance use measures, (3) psychological measures, (4) Behavioral Economic and (5) neuropsychological measures. Additionally, participants will complete questionnaires assessing their experience while using 1) the moderation strategies detailed above and 2) [for participants using the mobile application] specific questions regarding use of the application (e.g. The mobile application was easy to use; I would use this mobile application to help monitor my alcohol use). The follow-up measures will be administered via email and collected through Qualtrics online survey platform.

3f. Check all research activities that apply. *Attach a copy of materials to be used (e.g., interview/focus group questions, instruments, data collection forms, etc.).*

☐	Anesthesia (general or local) or sedation	☐	Magnetic Resonance Imaging (MRI)
☐	Audio, video, digital, or image recordings	☐	Materials that may be considered sensitive, offensive, threatening, or degrading
☐	Biohazards (e.g., rDNA, infectious agents, select agents, toxins)	☐	Non-invasive medical procedures (e.g., EKG, Doppler)
☐	Biological sampling (other than blood)	☐	Observation of participants (including field notes)
☐	Blood drawing, injections, surgical procedures (including biopsies) ▯ Complete Appendix Q	☐	Oral history (does not include medical history)
☐	Coordinating Center	☐	Placebo
☐	Data, not publicly available	☐	Pregnancy testing
☐	Data, publicly available	☐	Radiation (e.g., CT or DEXA scans, X-rays, nuclear medicine procedures) ▯ Complete Appendix V
☐	Data/Specimen storage/repository ▯ Complete Appendix C (future unspecified use, including research databases for purposes of sharing data or specimens collected with other researchers/studies in the future)	☐	Record review (which may include PHI)
☐	Deception ▯ Complete Appendix D & Appendix M1	☐	Specimen research
☐	Devices ▯ Complete Appendix E	☐	Stem cell research
☐	Diet, exercise, or sleep modifications	☐	Surveys, questionnaires, or interviews (one-on-one)
☐	Drugs or biologics ▯ Complete Appendix F	☐	Other:
☐	Emergency research		Specify:
☐	Focus groups		
☐	Food supplements		
☐	Gene transfer		
☐	Genetic testing ▯ Complete Appendix G		
☐	Internet or e-mail data collection		

3g. Estimate the time required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

The baseline and outcome sessions will take approximately 2 hours each.

Section 4 - PARTICIPANT POPULATION

4a. What is the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking Kent State IRB approval?

The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

64 participants

4b. Explain how this number was derived (e.g., statistical rationale, attrition rate, etc.).

Sample size was determined by conducting a power analysis for power = 0.80 at α = .05 [16] using G*Power version 3.1 software [17]. In order to ensure that all main hypotheses are adequately powered we utilized the smallest effect size (f=.13) indicated among our primary outcomes to calculate the required sample within a repeated measures, between-within factor framework, with two groups and two repetitions. This analysis resulted in an estimated sample size of n=64, actual power = .811.

4c. Specify the age(s) of the individuals who may participate in the research:

Age(s): **21-65**

4d. Specify the participant population(s) to be included (check all that apply):

☒	Adults	☐	Pregnant women/fetuses → Complete Appendix K (Only if pregnant women are *intentionally* recruited and/or studied)
☐	Adults with decisional impairment → Complete Appendix W	☐	Prisoners → Complete Appendix L
☐	Children (< 18 years) → Complete Appendix I. Research involving minors must adhere to University policy 5-19.	☒	Student research pools (e.g., psychology, sociology, communication) → Complete Appendix Y
☐	Neonates (uncertain viability/nonviable) → Complete Appendix K	☐	Unknown (e.g., research using secondary data/specimens, non-targeted surveys)
☐	Non-English speaking → Complete Appendix J	☐	Other Specify:

The regulations require that, "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." 45 CFR 46.111(b). There are additional, explicit regulatory requirements regarding pregnant women and fetuses (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C) and children (45 CFR 46 Subpart D and 21 CFR 50 Subpart D. The questions in the applicable appendices address these additional requirements.

4e. Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

Participants will include individuals age 21 years or older endorsing at least three negative consequence of alcohol use in the past month, additional exclusion / inclusion described previously, but who are not interested in seeking treatment from a health care professional. It is necessary to include only individuals age 21 or older to comply with state and federal law regarding alcohol use. It is necessary to include individuals

46.111(A)(3) Selection of subjects

who endorse at least one negative consequence of alcohol use as those not experience even mild problems related to alcohol use would not be likely to have an interest in using the proposed applications. It is necessary to exclude those seeking treatment as the conditions proposed in the current study have no demonstration of efficacy.

4f. Will any participants be **excluded** based on age, gender, race/ethnicity, medical conditions, pregnancy status, language, education, or financial status?

☒ Yes

☐ No

If Yes Explain the criteria and reason(s) for each exclusion. Explain who will evaluate and make determinations about subjects that should be excluded from the study. *Consider the study's scientific or scholarly aims and risks.*

Age – under 21 not legally allowed to consume alcohol

Language – Must be English proficient (in order to comprehend questionnaire items, etc.)

Section 5 – RISK/BENEFIT ASSESSMENT

5a. Do you think that the probability and magnitude of harm or discomfort anticipated for the participants are greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests?

☐ Yes

☒ No

If Yes Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. Include the following:

- The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected);
- Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee);
- Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled); and
- Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems).

5b. Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence. As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. Consider the range of risks, including physical, psychological, social, legal, and economic.

Overall, the risks of this study are considered minimal, and include (1) possible emotional discomfort from answering sensitive questionnaire items and (2) breaches of confidentiality.

5c. Describe how risks, harms, and/or discomforts will be minimized. *If testing will be performed to identify individuals who may be at increased risk (e.g., pregnant women, individuals with HIV/AIDS, depressive disorders, etc.), address timing and method of testing; include how positive test results will be handled.*

(1) Some questionnaire items used may be considered sensitive to some participants (disclosing information about their drinking habits), and as such, may result in distress. However, care has been taken to minimize these risks by making these procedures explicit during the informed consent process, by noting their use in the instructions on specific tasks, and by reminding participants of their right to withdraw from the study at any time. These risks are thought to be minimal.

(2) Breach of confidentiality (judged highly unlikely). The risks of a breach of confidentiality will be addressed by emphasizing that information obtained during assessments is confidential and will be used solely for research. In addition, all records will be kept in locked or password-protected files, and stored in either locked offices and/or secure servers maintained by Kent State. These records will be accessed only by essential study staff who are trained in human subject's protection guidelines. In addition, all questionnaire data will contain only numeric codes, with identifying information and link codes kept in a separate, password-protected database. All assessment procedures will be closely supervised, and study staff will be trained and reminded of the need to keep all information confidential. No names will be used in presenting data in lectures, seminars, and papers.

5d. List the potential benefits that individual participants, society or both may expect as a result of this research study. State if there are no direct benefits to individual participants. *Compensation is not to be considered a benefit.*

Society may benefit from the development of applications aimed at helping people reduce negative consequences of alcohol use. No direct benefits are expected for participants given that the mobile application is in developmental stage and has no demonstration of efficacy.

5e. Discuss how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

Participants will be told that they should expect no personal benefit from participating in the study. Participants will be involved in research that has potential to inform interventions for smoking and benefit the scientific community.

The risk-benefit ratio of this study is favorable. Risks of adverse events associated with the study procedures are minimal.

5f. Is it possible that this study will discover a previously unknown condition such as a disease, suicidal intentions or genetic predisposition in a participant as a result of the study procedures?

☐ Yes
☒ No

If Yes Explain how you will manage the situation.

5g. Will this study collect information about research participants' family history that includes personal identifiers (e.g., secondary subjects)?

☐ Yes Complete Appendix P
☒ No

5h. Is this a double blind randomized study in which neither the participants nor the research team knows the assignment to the study drug or placebo?

☐ Yes
☒ No

If Yes Describe the unblinding plan

Section 6 - PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION

6a. Specify the recruitment methods for this study and attach a copy of recruitment material(s):

- ☐ Personal contact
- ☐ Contact or approach letters
- ☐ Telephone calls (include script)
- ☐ Brochures
- ☐ Printed advertisements
- ☐ Flyers
- ☐ Internet
- ☐ Home visits
- ☐ Radio or TV (include written text of the advertisement and brief layout of images)
- ☐ Email (include copy of text to be used)
  Specify frequency:
- ☒ Other
  Specify: **SONA system**

6b. Who will approach or recruit potential participants?

☐ Principal Investigator and/or Co-Investigator
☐ Research Staff
☒ Other please describe: **Recruited via SONA**

6c. Does the person recruiting have what could be perceived as a supervisory role or position of authority (e.g., teacher, counselor, doctor) by the potential participant(s)?

☐ Yes
☐ No

If Yes Describe how you will minimize risks for participants to feel obligated to participate in the research (e.g., will the potential participants be afforded the opportunity to take material home and discuss the study with family members and/or primary care providers? Will the person recruiting emphasize the voluntariness of participation? If so, explain how.)

Participants will be notified that the study is completely voluntary, that they can quit at any time, and will be given a link to access other SONA studies in which they may earn credit.

6d. When/how often will participants be recruited? (e.g., before/after a counseling visit, via email with 3 reminders sent at specific intervals).

Participants will be notified that they may meet criteria for the study based on their responses on the SONA mass screener. Community members interested in participating are able to contact the lab via phone to complete a brief eligibility screen after providing verbal consent.

6e. Where will participants be recruited? (e.g., doctor's office, classroom, online)

Online – SONA system; Community locations via flyers (i.e. coffee shops, restaurants)

6f. What steps will be taken to avoid coercion or undue influence in the *recruitment* of research participants? (e.g., will the potential participants be afforded the opportunity to take material home and discuss the study with family members and/or primary care providers?)

Participants will be given unlimited time to decide whether or not to participate in the study and will be provided with a list of alternative studies.

Section 7 - INCENTIVES or COMPENSATION TO PARTICIPATE

46.116 General requirements for informed consent.

7a. Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement) to participate in the research study?

☒ Yes ☐ No

Compensation plans should be pro-rated (not contingent upon study completion) and should consider participation withdrawals, as applicable.

If Yes ▯ Describe the compensation/incentive. Include the amount and timing of all payments.

Participants will receive classroom (SONA) credit to participate in the research study, or $80 if they are recruited from the community.

7b. Have you reviewed and complied with the Procedures for Compensating Research Participants policy that is available on our website at: https://sites.google.com/a/kent.edu/division-of-research-and-sponsored-programs-intranet/home/office-of-research-compliance/irb/forms

☒ Yes ☐ No

Section 8 - INFORMED CONSENT PROCESS

The human subject protection regulations at 45 CFR 46:

- *List ten basic elements of information that must be provided to subjects when investigators are seeking informed consent from subjects to participate in research (unless the IRB approves a request for a waiver/alteration of any/all of the basic elements for consent.) The basic elements of consent are:*

• *Purpose, procedures and expected duration of the research* • *Risks and discomforts* • *Potential benefits* • *Alternative procedures or treatments (if any)* • *Compensation for participation in the research (if any)*	• *Provisions for confidentiality* • *Management of research related injury* • *Contacts for additional information* • *Voluntary participation and the right to discontinue participation without penalty*

- *Require that participants sign a consent form (unless the IRB approves a request for a waiver of documented consent.)*

If participants cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, consent from a legal representative (such as a parent or legal guardian) is required. To develop a consent form, begin by using the consent form template that is available from our website.

8a. Who will discuss and obtain consent from participants?

☐ Principal Investigator
☒ Research key personnel
☐ Other: Specify

8b. Are you requesting approval for a waiver/alteration of any/all of the basic elements of consent (see information above) for any part of the research?

(e.g., investigators conducting research that involves deception might request a waiver/alteration of the basic elements of consent so that the true purpose of the research is not disclosed in the consent form.)

☐ Yes▯ Complete **Appendix M1**
☒ No

8c. Are you requesting a waiver of the requirement for participants to sign a consent document?

(e.g., an investigator conducting research that only involves the use of anonymous surveys might request a waiver of signed consent.)

☐ Yes▯ Complete **Appendix M2**
☒ No

46.117 Documentation of informed consent

8d. Describe who will provide consent or permission (i.e. participant, legally authorized representative, parent and/or guardian)? ☐ N/A

Participant will provide consent.

8e. Check all that apply:

☒	Informed Consent– Signed Form **Provide copies of document. Please use website template**	☐	Parental Permission – Form
☒	Informed Consent – Verbal Script/Online/Unsigned form **Provide copies of script/document**	☐	Parental Permission – Verbal Script/Online/Unsigned
☐	Assent – Form	☐	Translated Consent/Assent – Form(s), Script(s), etc. *(provide copy of English version with description the qualifications of the translator.)*
☐	Assent – Verbal/Online/Unsigned	☐	Photograph/video/audio taping consent form (or permission for photographs/video/audiotaping included as section on informed consent)
☐	Not Applicable (existing data or specimens)	☐	Other (Specify):

8f. Describe the consent process. Explain *when* and *where* (e.g., in a private room, in a group setting) consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g., waiting period, if any) to consider participation. *If the person consenting subjects into the study has what could be perceived as a supervisory role (professor, teacher, doctor, counselor, etc…) in the eyes of the subjects, explain how risks will be minimized for participants to feel obligated to participate in the research.*

46.111 and 46.117 Documentation of Informed consent and

Consent will be performed at the beginning of the laboratory session in a private room. All study procedures will be explained to the participant and the research team member obtaining consent will answer any questions posed by the potential participant. Following this, participants will be given an indefinite period of time to review the consent and consider participation in the study.

8g. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?

☐ Yes **Provide copies of these tools**

☒ No

Section 9 - HIPAA RESEARCH AUTHORIZATION

9a. Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study?

PHI is individually identifiable health information, held or maintained by a covered entity (healthcare provider, insurance company, health plan, medical center) or its business associates acting for the covered entity. Covered entities may use or disclose health information that is de-identified without restriction under the Privacy Rule. Covered entities seeking to release this health information must determine that the information has been de-identified using either statistical verification of de-identification or by removing certain pieces of information. For more information, see De-identifying PHI Under the Privacy Rule.

☒ No

☐ Yes ▯ **Check all that apply below.** *In general, covered entities can use and disclose PHI for research if authorized to do so by the subject in accordance with the Privacy Rule. In addition, in certain circumstances, the Rule permits covered entities to use and disclose PHI without Authorization for certain types of research activities.*

☐ Written Authorization ▯ **Provide a copy of the Authorization Form**

An authorization is a detailed written document requesting patient-subject permission for disclosure and use of PHI for a specific purpose. This is different from the consent form. HIPAA regulations describe specific elements that must be present in an authorization form. Authorization is required by HIPAA for disclosures or uses other than for treatment, payment, or health care operations. Refer to the HIPAA template on our website.

☐ Partial Waiver of authorization (recruitment purposes only; preparatory to research) ▯Complete **Appendix N**

☐ Full Waiver of authorization (limited data set with no direct identifiers and with a data use agreement; information on descendant's) ▯ Complete **Appendix N**

Section 10 - PRIVACY OF PARTICIPANTS

10a. Describe the provisions to protect the privacy interests of the participants.

Consider the circumstances and nature of information to be obtained, taking into account factors (e.g., age, gender, ethnicity, education level, etc.) that may influence participants' expectations of privacy. For example, individuals might not want to participate in a study that involves their being seen entering a building that might stigmatize them, such as a substance abuse counseling center, or to provide personal information during an interview conducted in a crowded place (e.g., clinic waiting room). Protecting the privacy interests of a young child might mean having a parent present at a session with an investigator, while protecting the privacy interests of a teenager might mean having the parent absent from the session.

All information obtained during the online assessment and laboratory sessions is confidential and will be used solely for research purposes. All digital records will be collected via Qualtrics survey. The data will be hosted on Kent State University's secure server and will be password-protected to ensure that only essential research staff will have access to Qualtrics survey data will be downloaded weekly, and entered into a password protected data file that will be stored on the Kent State University severs. Study items and participant contact information will be collected in separate surveys. In a separate database (which is itself password-protected), participants' identifying and contact information will be stored and linked to a unique study code, which will be used to connect this information to their study data during the duration of the study. After all study procedures are complete, the database containing all participant identifying information, as well as their unique study codes, will be destroyed, resulting in a de-identified final dataset.

Informed consent documents will be kept in a locked file that is available only to essential research personnel who have been trained in human subject's protection guidelines. Any study measures that are collected on paper (including those administered during the phone screening process) will contain only participants' unique study ID numbers, and no identifying information, and will be kept in a separate, secure location. All research staff will be trained and reminded of the need to keep all information confidential.

CFR 46.111 (7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

10b. Does the research require access to personally identifiable private information? ☐Yes ☒No

If Yes ▯ Describe the personally identifiable private information involved in the research. List the information source(s) (e.g., educational records, surveys, medical records, etc.).

10c. Explain any circumstances (ethical or legal) where it would be necessary to break confidentiality. ☐ N/A

10d. Will this study obtain IDENTIFIABLE information from students' *educational* records? ☐ Yes ☒ No

If Yes Does the individual obtaining the information have legitimate access (e.g. as the student's teacher/professor)? ☐ Yes ☒ No

The FERPA (Family Educational Rights and Privacy Act) applies when student educational records are used for research. FERPA requires a signed permission when IDENTIFIABLE information from student records is released to anyone who did NOT already have legitimate access.

Section 11 - CONFIDENTIALITY OF DATA

11a. What format will be used to store participant information? Check all that apply.

- ☒ Hardcopy paper documentation
- ☒ Database system
- ☐ Disk (CD ROM, floppy disk, flash drive)
- ☐ Audio Tapes
- ☐ Video Tapes
- ☐ Other--Specify:

11b. How will the participant information be kept secure and confidential? Check all that apply.

- ☒ File cabinets with combination or key lock
- ☐ Locked room with cardkey access
- ☐ Off-site backup vendor
- ☒ Electronic records with user identification/password
- ☐ Biometric authentication (e.g. fingerprints, voice, retinal/iris scan
- ☐ Freezer with a padlock
- ☐ NIH Certificate of Confidentiality
- ☐ Other --Specify:

11c. Will you be retaining identifying information for purposes of another research project (e.g. keeping participants' contact information to recruit them for future research)? ☒ Yes ☐ No

If Yes Describe what information will be retained. *The information must also be described in the consent form.*

Will retain contact information of participants interested in finding out about other studies which they may be eligible/interested.

CFR 46.111 (7) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

11d. How will access to participant information be revoked when a staff member leaves the study? *(E.g., computer passwords will be changed or key cards will be returned to the P.I.)*

Access will be removed from key cards & online servers; computer & document passwords will be changed

11e. Will you be sharing or receiving research *data* for this project with/from researchers outside of Kent State University?	☐ Yes provide copy of Data Use Agreement ☒ No
11f. Will you be sharing or receiving *materials or specimens* for the purposes of this project with/from researchers outside of Kent State University?	☐ Yes complete a Materials Transfer Agreement ☒ No

11g. Indicate what will happen to the identifiable data at the end of the study. *Research data should be retained for a minimum of three years after final project closeout (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.)*

- ☐ Identifiers will be permanently removed from the data and destroyed (de-identified)
- ☒ Identifiable/coded (linked) data will be retained and stored confidentially
- ☐ Identifiable data will be retained and may be made public with participant consent (e.g., ethnographic research)
- ☐ Identifiable data were not collected

Section 12 – COST TO PARTICIPANTS or REIMBURSEMENTS

12a. Are there any potential costs that participants (or their insurers) will incur as a result of study participation *(e.g., parking, study drugs, diagnostic tests, etc.). This information should be disclosed in the consent form.*	☐ Yes ☒ No
If Yes	
12b. Are there any costs to participants that will be covered/reimbursed by the research study.	☒ Yes ☐ No
If Yes **Parking**	

46.116 (b)(3) General requirements for informed consent

Section 13 - ASSURANCE: PRINCIPAL INVESTIGATOR

I agree to follow all applicable policies and procedures of Kent State University and federal, state, and local laws and guidance regarding the protection of human subjects in research, as well as professional practice standards and generally accepted good research practice guidelines for investigators, including, but not limited to, the following:

- Perform the research as approved by the IRB with appropriately trained and qualified personnel with adequate resources;
- Initiate the research only after written notification of IRB approval has been received;
- Obtain and document (unless waived) informed consent and HIPAA research authorization from human subjects (or their legally authorized representatives) prior to their involvement in the research using the currently IRB-approved consent form(s) and process;
- Promptly report to the IRB events that may represent unanticipated problems involving risks to subjects or others;

- Provide significant new findings that may relate to the subjects willingness to continue to participate;
- Inform the IRB of any proposed changes in the research or informed consent process before changes are implemented, and agree that no changes will be made until approved by the KSU IRB (except where necessary to eliminate apparent immediate hazards to participants);
- Complete and submit a Continuing Review of Human Subjects Research application before the deadline for review at intervals determined by the IRB to be appropriate to the degree of risk (but not less than once per year) to avoid expiration of IRB approval and cessation of all research activities;
- Maintain research-related records (and source documents) in a manner that documents the validity of the research and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;
- Retain research-related records for audit for a period of at least three years after the research has ended (or longer, according to sponsor or publication requirements) even if I leave the University;
- Contact the Research Compliance for assistance in amending (to request a change in Principal Investigator) or terminating the research if I leave the University or am unavailable to conduct or supervise the research personally (e.g., sabbatical or extended leave);
- Provide a Final Study Report to the IRB when all research activities have ended (including data analysis with individually identifiable or coded private information); and
- Inform all Co-Investigators, research staff, employees, and students assisting in the conduct of the research of their obligations in meeting the above commitments.

Please type your name in the space below and send from your kent.edu email account. verify that the information provided in this Use of Human Subjects in Research application is accurate and complete.

W. V. Lechner — Signature of Principal Investigator

3/23/2018 — Date

1. Sobell, M.B., et al., *Developing a prototype for evaluating alcohol treatment effectiveness*, in *Evaluating alcohol and drug abuse treatment effectiveness: Recent advances*, L.C. Sobell, M.B. Sobell, and E. Ward, Editors. 1980, Pergamon Press: New York.
2. Greenwald, A.G., D.E. McGhee, and J.L. Schwartz, *Measuring individual differences in implicit cognition: the implicit association test.* J Pers Soc Psychol, 1998. **74**(6): p. 1464-80.
3. Houben, K. and R.W. Wiers, *Response inhibition moderates the relationship between implicit associations and drinking behavior.* Alcohol Clin Exp Res, 2009. **33**(4): p. 626-33.
4. Sheehan, D.V., et al., *Reliability and validity of the mini international neuropsychiatric interview for children and adolescents (MINI-KID).* The Journal of clinical psychiatry, 2010. **71**(3): p. 313-326.
5. Kuntsche, E. and S. Kuntsche, *Development and Validation of the Drinking Motive Questionnaire Revised Short Form (DMQ–R SF).* Journal of Clinical Child & Adolescent Psychology, 2009. **38**(6): p. 899-908.
6. Stein, L.A.R., et al., *Validity and Reliability of the Alcohol Expectancy Questionnaire-Adolescent, Brief.* Journal of child & adolescent substance abuse, 2007. **16**(2): p. 115-127.
7. Hogue, A., S. Dauber, and J. Morgenstern, *Validation of a Contemplation Ladder in an Adult Substance Use Disorder Sample.* Psychology of addictive behaviors : journal of the Society of Psychologists in Addictive Behaviors, 2010. **24**(1): p. 137-144.
8. Kramer, J.H., et al., *NIH EXAMINER: conceptualization and development of an executive function battery.* Journal of the International Neuropsychological Society, 2014. **20**(1): p. 11-19.
9. Reynolds, B. and R. Schiffbauer, *Measuring state changes in human delay discounting: an experiential discounting task.* Behav Processes, 2004. **67**(3): p. 343-56.

10. MacKillop, J., et al., *Delayed reward discounting and addictive behavior: a meta-analysis.* Psychopharmacology, 2011. **216**(3): p. 305-321.
11. Whiteside, S.P., et al., *Validation of the UPPS impulsive behaviour scale: a four-factor model of impulsivity.* European Journal of Personality, 2005. **19**(7): p. 559-574.
12. Watson, D., L.A. Clark, and A. Tellegen., *Development and validation of brief measures of positive and negative affect: the PANAS scales.* Journal of personality and social psychology, 1988. **54**(6): p. 1063-1070.
13. Radloff, L.S., *The CES-D Scale: a self-report depression scale for research in the general population*, in *Anonymous Applied Psychological Measurement*. 1977, West Publishing Co.: New York, NY. p. 385-401.
14. Nakonezny, P.A., et al., *Evaluation of anhedonia with the Snaith-Hamilton Pleasure Scale (SHAPS) in adult outpatients with major depressive disorder.* J Psychiatr Res, 2015. **65**: p. 124-30.
15. Spitzer, R.L., et al., *A brief measure for assessing generalized anxiety disorder: the GAD-7.* Arch Intern Med, 2006. **166**(10): p. 1092-7.
16. Cohen, J., *A power primer.* Psychological Bulletin, 1992. **112**(1): p. 155-159.
17. Faul, F., et al., *Statistical power analyses using G* Power 3.1: Tests for correlation and regression analyses.* Behavior research methods, 2009. **41**(4): p. 1149-1160.