Title: Text Assessment and Mobile Messaging Intervention to Reduce Problem Drinking

Principal Investigator: Jonathan Morgenstern, Ph.D.

Sponsor: National Institute on Alcohol Abuse and Alcoholism

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions.

This consent form will explain:
- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
The purpose of this study is to help us understand the role of computerized feedback with or without different kinds of text messaging in helping individuals reduce their drinking. You are being asked to participate in this study because you have indicated you are interested in reducing your drinking using technology.

How many people will take part in this study?
This research study hopes to enroll 900 men and women.

How long will you be in this study?
If you choose to take part in this study, the study procedures will last for 18 months (6 months of messages). You will not be asked to attend any in-person visits.

What will happen in this research study?
You have already completed some of the screening procedures for the study, but your formal consent to participate must be obtained before we can determine your eligibility. Once we have your consent to be in the study, we will complete the first assessment or “screening appointment” either over the phone or via live chat, depending on your preference, to determine if the study is appropriate for you.
If we confirm that you are eligible for the study based on your screening appointment, you will then complete an online assessment that lasts about 40 minutes. The online assessment includes questions pertaining to your drinking behaviors, the benefits and consequences of your drinking and questions about your thoughts and behaviors.

You will then be randomized into one of three different supportive text messaging groups. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being placed in any of the groups. The groups that you can be randomized into are:

- Group A: feedback with drink tracking;
- Group B: feedback with weekly mobile assessment and once a day messaging based on your assessment responses;
- Group C: feedback with weekly mobile assessment and at least once a day messaging based on your assessment responses.

Regardless of your randomization group, you will receive text messages that ask you questions about your drinking and how you are feeling. You may also receive messages designed to help you reduce your drinking over the six-month period, depending on the group you are randomized into. You will be informed of which group you have been randomized into after your screening appointment and online assessment have been completed.

As part of this study, you are agreeing to send and receive text messages on your mobile phone. You will receive at least four text messages a week and be required to send a minimum of four text messages a week. The four texts you receive will ask you questions about your drinking, and will require a response from you. However, as part of the protocol you may be sending and receiving up to 30 text messages a week. If you are concerned about receiving text messages that explicitly refer to alcohol or drinking, you have the option to receive text messages that make no mention of or reference to alcohol or drinking.

There are six assessment points throughout the course of the 18-month study, during which you will be asked to complete an online survey. The assessment points are as follows: baseline and at months 1, 3, 6, 12 and 18. During all research assessments, you will be asked about your drinking and other drug use, and your physical and emotional well-being. You will answer these questions online using your computer, tablet, or mobile phone.

This information is being collected for research purposes only so that the researchers can gain a better understanding of how to help people change their drinking. All of your data will be stored with a unique code rather than any personally identifying information. You may ask contact the researchers at any time to ask questions about anything you do not understand. You can refuse to answer any questions that you do not feel comfortable answering, and you can refuse to complete the assessment by stopping at any time.

You will use your computer or tablet to complete your longer assessments, which will be emailed to you, and your cell phone for your short weekly assessments, which will be sent to you via text message.
Your cell phone number will be used for this study. Text messages will be sent to your phone that will ask you questions about your drinking and/or offer you support to reach your goals.

**What are the risks of the research study? What could go wrong?**

**Collection of Sensitive Information:**
Some of the questions you may answer throughout the study, whether it’s over the phone or via live chat with a research staff member, or on the regular assessment surveys via email or on your mobile phone, may seem very personal or embarrassing. They may upset you. You may skip any question that you do not want to answer. If the questions make you very upset, we will offer you the opportunity to speak with a counselor.

You may not appreciate receiving a text message or its content at a particular time. If you do not wish to answer a particular question at the time you receive the message, you may skip it.

**Data Use Overage:**
If you do not have an unlimited text messaging plan you may be charged for the text messages you send and receive in this study. We will not compensate you for any charges you incur for text messages.

**Text Message Security:**
As with any mobile phone, there is a risk that messages you send and receive can be read by unintended individuals. It is your responsibility to ensure your phone is appropriately secured and managed; however, we will provide you with ways to keep your messages confidential and your phone secured.

**Technical Difficulties:**
There may be days on which you receive no text messages, times when you might expect a text message and do not receive one, and days on which your text queries go unanswered due to failures in message transmission, message processing, network problems, or problems with your phone. These issues may also cause messages to be deleted from your phone company’s server. If this occurs, please contact us.

**Randomization:**
Your group may receive less effective treatment or have more side effects than the other groups.

**What are the benefits of this research study?**
The possible benefits you may experience by participating in this study include a decrease in your drinking; however, this cannot be guaranteed. The information we learn from this study may help individuals attempting to reduce their drinking through improvements in services and programs.

Although we do not currently know which group will be most effective, it is possible that your group may receive more effective messages to help you reduce your drinking.
If you do not want to take part in this research study, what are your other choices?
You do not have to participate in this study to receive technology-based assistance to reduce your drinking. Currently, many websites exist where you can obtain information about your drinking or referrals to in-person services. If you would like, we can provide you with a list of available online resources. To our knowledge, there are no other text messaging programs for drinking at this time.

Are there any costs for being in this research study?
This research study is funded by The National Institute of Alcohol Abuse and Alcoholism (NIAAA). You will not have any added costs from being in this study. All study related procedures will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research.

Will you receive any payments for participating in this research study?
As part of the study, you will be paid $20 to complete the baseline assessment; $5 to complete the 1-month assessment; $10 to complete the 3-month assessment; $20 to complete the 6-month assessment; and $15 for the 12- and 18-month assessments; for a total of $80. If you do not complete the entire study, you will be paid for the number of assessments that you have completed. The payment will be in the form of an electronic gift card to Amazon or Starbucks, which will be emailed to you at the end of the study or when you end your participation. Again, you will NOT be compensated for any costs you may incur by sending and receiving individual text messages.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB - the committee that oversees research at this institution).

Reasons for withdrawal may include:
- Failure to follow instructions
- Failure to complete assessments
- It is not in your best interest to continue on this study
- The study is stopped

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.
What happens if new information is learned?
You will be told any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of questionnaires and interviews. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside the Northwell Health, except as detailed below.

Investigators will share information collected from this research study with:
- The study sponsor, National Institute on Alcohol Abuse and Alcoholism (NIAAA),
- The Partnership for Drug-Free Kids, who will have access to your phone number to send you the text messages,
- The Data and Safety Monitoring Board (DSMB),
- Clinical staff not involved in the study who may be involved in participant’s treatment, health insurers or payers.

The following reviewers may access your study and medical records to make sure that this study is being done properly:
- Representatives from federal and state government oversight agencies, such as National Institutes of Health,
- Representatives from the Solutions Institutional Review Board (IRB - the committee that reviews research at this institution),
- Representatives from the study sponsor, National Institute on Alcohol Abuse and Alcoholism (NIAAA).

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it will be released to others. If this happens, your information may no longer be protected by the federal law. However, these agencies are under strict guidelines to protect your information and only access the minimal information needed to conduct their duties.

We may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.
Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the Principal Investigator at the following address:

Dr. Jonathan Morgenstern
1010 Northern Boulevard
Suite 311
Great Neck, NY 11021

Your letter needs to say that you have changed your mind and do not want the researchers to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Does the investigator of this study receive money if you take part?
The investigators on this study will receive money that is directly related to your participation in this study. Funding for this research study is provided by National Institute on Alcohol Abuse and Alcoholism (NIAAA), money they receive is to pay them back for the costs of conducting the research study. The amount of money they receive is based upon the number of people enrolled in the study. If your doctor is an investigator for this study s/he is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.
Who can answer your questions about this study?
If you have any questions about the study, or the side effects or injury caused by research, you may call Dr. Jonathan Morgenstern at (516) 837-1677. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (IRB - the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.
Consent Form Questionnaire:

A Note from the Text Assessment and Mobile Messaging Intervention to Reduce Problem Drinking Team: Because you are completing this study away from our offices, we use the following questions to make sure that you fully understand what we are asking you to do as a participant in this research project. We will review this consent form and quiz with you on the phone. We wish to underscore that this quiz is not designed to challenge your commitment to the study or your drinking goals, but to ensure your safety and your eligibility to participate.

Please read the following questions and select True or False:

1. I need to use my mobile phone for this study.
   True    False

2. I will be receiving between 4-30 text messages a week.
   True    False

3. I will be compensated for my participation in this study.
   True    False

4. I will receive up to $80 for my participation in this study.
   True    False

5. The text messages are stored on my phone company’s server.
   True    False

6. Once the study begins, I cannot drop out regardless of the circumstances.
   True    False

7. While I will be taught how to safeguard my privacy on my phone and in the text messages, it is my responsibility to protect the content I store on my phone.
   True    False

8. If the researchers believe I pose a risk to myself or others, they may call the appropriate authorities to keep me and others safe.
   True    False
9. A unique code identifies me when I complete my questionnaires.
   True                              False

10. This study lasts for two months.
    True                              False
**summation/signature**
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____________________________________________________________
Printed Name of Participant

_____________________________________________________________    __________
Signature of Participant           Date

_____________________________________________________________
Witness’s Printed Name

_____________________________________________________________    __________
Witness’s Signature           Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

**investigator’s statement**
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study, and answered any further questions relating to it.

_____________________________________________________________
Investigator’s Printed Name

_____________________________________________________________    __________
Investigator’s Signature           Date