R01AA026596, Ondersma & Yonkers e-SBI for alcohol use in pregnancy trial

National Clinical Trial (NCT) Identified Number: NCT04332172
Principal Investigator: Steven J. Ondersma and Kimberly A. Yonkers
Sponsor: National Institute on Alcohol Abuse and Alcoholism (NIAAA) of the National Institutes of Health (NIH)

Grant Title: Scaling up: A multi-site trial of e-SBI for alcohol use in pregnancy
Grant Number: R01AA026596
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Research Participant Information and Consent Form

Study Title:	Women's eHealth Study: Participant Trial
Researcher and Title:	Steven J. Ondersma, PhD Professor
Department and Institution:	Department of Obstetrics & Gynecology Division of Public Health Michigan State University
Contact Information:	517-884-6031
Sponsor:	National Institutes of Health

BRIEF SUMMARY

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study of software designed to help pregnant women choose to avoid using any alcohol while pregnant. Your participation in this study will take about 3 hours over approximately the next 8 months. You will be asked to answer questions and work with the software using your own smartphone or tablet (today's questions will take about 40 minutes). You may also receive at random (like with a coin flip) various types of information designed to help you have a healthy pregnancy (5 minutes each time if you receive this information). You may also be selected to receive text messages from us twice per week. You will be asked to answer a brief set of questions three separate times using your own smartphone or tablet (5 minutes each time), plus a longer set of questions one time (approximately 40 minutes).

The most likely risks of participating in this study are that you might feel distressed by some of the personal questions, or you may feel embarrassed if anyone should somehow see your answers.

The potential benefits to you for taking part in this study are that you might have a healthier pregnancy or healthier baby.

PURPOSE OF RESEARCH

- You have been selected as a possible participant in this study because you are pregnant and because you met eligibility criteria, including criteria for alcohol use. (Note that these criteria are broad, and so include a wide range of alcohol use patterns.)
- From this study, the researchers hope to learn whether some combinations of information and text messages are more helpful than others. We will be testing three separate pieces of technology. The first is a 20-minute educational session that women will complete using their own smartphone or tablet. The second is two additional 5-minute sessions that we will also ask women to complete using their own smartphone or tablet. The third is text messages, which will be sent twice per week. All of these procedures are extra and experimental.

Approved by a Michigan State University Institutional Review Board effective 9/24/2024.
This version supersedes all previous versions. MSU Study ID STUDY00005298.

- Your participation in this study will take approximately 3 hours, depending on which of the technology pieces you are asked to do. Some women will be asked to do all three, others will be asked to do only two of them, and some women will be asked to do just one of them. Some women won't be asked to do any of them, but all women will be asked to answer 5 minutes of questions using their own smartphone or tablet, three separate times, plus 40 minutes of questions another time.
- In the entire study, 384 people are being asked to participate.

WHAT YOU WILL BE ASKED TO DO

If you take part in the study, you will be asked to do the following:

- Answer questions on your smartphone or tablet about your health, relationships, and substance use before and during pregnancy.
- After this, the software will randomly decide whether you will receive software-based feedback on how to have a healthy pregnancy, plus information on how to find services; or you will just receive the information on how to find services.
    - Half of the women selected to receive the feedback from the software will also receive two additional sessions during their pregnancy.
        - If you are in this group, you will complete these additional sessions using your own smartphone or tablet.
        - Links to these sessions will be sent 6 weeks following your first session and when you are 30 weeks pregnant.
        - You can complete these sessions from anywhere.
    - You will also be told if you are randomly selected to receive twice weekly text messages designed to help you have a healthy pregnancy.
        - If you are in this group, the text messages will start after you complete your first session.
        - Some of the text messages will be about your alcohol use and pregnancy.
        - You can reply "STOP" at any time to end these messages.
    - The group you are randomly placed into by the software will be clearly described to you.
- <u>After today, you will be asked to complete a total of four questionnaires using your smartphone or tablet</u>. This will happen regardless of the group you are part of, meaning that all participants in this study will be asked to answer these questions. <u>Three of them will be brief (5 minutes each) and one will be longer (40 minutes).</u>
    - We will text and/or email you a link to complete a <u>brief</u> questionnaire at these three times: 4 weeks after today, when you are 27 weeks pregnant, and 4 weeks after you have your baby.
    - We will text and/or email you a link to complete the <u>longer</u> questionnaire when you are 34 weeks pregnant.

POTENTIAL BENEFITS

- The potential benefits to you for taking part in this study are that you may be helped to have a healthier pregnancy or healthier baby.
- Additionally, information from this study may benefit other people now or in the future.

POTENTIAL RISKS

The potential risks of participating in this study are:

- Emotional risks: You may feel distressed by some of the personal questions.
- Social risks: You might experience distress or embarrassment if someone were to see your answers or the text messages you receive and somehow connect them to you.
- There may also be additional risks or discomforts involved in taking part in this study that are not known to researchers at this time.

PRIVACY AND CONFIDENTIALITY

- The data for this project will be kept confidential and stored on secure servers.
- Information about you will be kept confidential to the maximum extent allowable by law.
- Although we will collect some identifying information about you, including internet protocol (IP) addresses, you will be identified in the research records by a code name or number.
    - Research data will be deidentified when the study is complete.
    - Identifiable information will be destroyed when no longer needed.
- Deidentified data will be submitted to the National Institute of Alcohol Abuse and Alcoholism Data Archive ($NIAAA_{DA}$).
    - Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Database (NIAAADA) at the National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about alcohol problems more quickly than before.

      During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

      You may not benefit directly from allowing your study data to be shared with NIAAADA. The study data provided to NIAAADA may help researchers around the

world learn more about alcohol problems and how to help others who have problems with alcohol. NIAAA will also report to Congress and on its website about the different studies using NIAAADA data. You will not be contacted directly about the study data you contributed to NIAAADA.

You may decide now or later that you do not want your study data to be added to the NIAAADA. You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAADA. If you know now that you do not want your data in the NIAAADA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to the NIAAADA, call or email the study staff who conducted this study, and they will tell NIAAADA to stop sharing your study data. Once your data is part of the NIAAADA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

- The following entities may also have access to your study information:
  - Researchers and Research Staff.
  - Institutional Review Board (IRB) at Michigan State University.
  - Study sponsor: National Institute of Health (NIH).
  - Federal agencies with appropriate regulatory oversight [e.g., Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.].
- The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.
- This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

  There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

  Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

- A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW

- Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.
- You have the right to say no.
- You may change your mind at any time and withdraw.
- You may choose not to answer specific questions or to stop participating at any time.
- The study PI may stop your participation in this study without your consent. The PI will make the decision and let you know if it is not possible for you to continue. Such a decision may be made to protect your health and safety, or because you did not follow the instructions to take part in the study.

COSTS AND COMPENSATION FOR BEING IN THE STUDY

- Participation in this study will be of no cost to you. However, text message and data rates may apply from your wireless carrier or internet service provider.
- You will be compensated for your time and inconvenience for taking part in this research study. You will receive Rewards Genius by Tango Card credit (hereafter "credit") as follows:
    - A credit of $40 for completing today's session.
    - Credits of $20 each for completing three brief follow-up surveys that we text to you (4 weeks after today, at 27 weeks gestation, and 4 weeks after you have your baby).
    - A credit of $50 for completing the longer follow-up link sent to you at 34 weeks gestation (plus a $20 bonus credit if you complete this 34-week survey within 24 hours of us texting you the link).
    - If you complete all parts of the study, plus earn the bonus, you will receive credits worth a total of $170.
- The credits can be used to obtain gift cards. You will be given access to a list of over 80 options from which you can choose the type of gift card (such as Amazon, CVS, or Walmart). You can also choose a debit card that will work like cash, but the value of debit cards is $3.00 less. For example, for today's session you could choose a $40 gift card to a store (like Amazon) or a debit card with $37 on it.
- If you do not finish the study, you will only be paid for the parts that you did complete.

RESEARCH RESULTS

- Clinically relevant research results, including individual research results will not be disclosed.

FUTURE RESEARCH

- Information that identifies you will be removed from the data collected for this study. The data collected for this study includes the survey questions you answer. After such removal, the data or lab results could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

CONTACT INFORMATION

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Dr. Steven Ondersma at 517-884-6031, or e-mail eHealth@msu.edu, or regular mail at Michigan State University; Department of Obstetrics & Gynecology, Division of Public Health; 200 East 1st Street; Flint, MI 48502.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

DOCUMENTATION OF INFORMED CONSENT.

Your signature below means that you voluntarily agree to participate in this research study.

_____ _____

Signature Date

You will be given a copy of this form to keep.