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Integrating mHealth for alcohol use disorders into clinical practice

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University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: Alcohol and Wellness: Testing the Integration of Smartphone Technology Into Primary Care

Formal Study Title: Integrating mHealth for Alcohol Use Disorders into Clinical Practice

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Welcome to Tula! Thank you for your interest in this study.
The following summary highlights the essential information you will need to decide whether to participate in this University of Wisconsin study funded by the National Institutes of Health. After you have reviewed this information, you can decide if you want to enroll in the study or not. You may reach out to the study team using the contact information provided to discuss any questions or concerns prior to joining the study. This process is called "informed consent."

- **What is this study about?**
  We are testing a smartphone app called "Tula" to help people improve their whole health and overall quality of life by reducing risks associated with alcohol use. Tula is a Sanskrit word that means "balance." Tula gives you access to information, strategies, and resources to help you live a healthier lifestyle. Being part of this study is not part of your regular health care and no information we collect will go in your medical record. The UW has strict rules to protect your personal and protected health information-PHI (identifiable details like name, birthday, address, etc).

- **Why we're doing the study.**
  The culture of drinking behavior in the US ranges from low-risk alcohol use to severe abuse or dependence. Drinking alcohol affects us in many ways. Efforts to reduce the risks associated with alcohol use is a public health priority. Health experts and government agencies have developed guidelines for moderate drinking, definitions for high-risk drinking patterns, and formal criteria for Alcohol Use Disorder, a chronic health condition.

- **What will happen in the study?**
  You will be randomly assigned to 1 of 3 groups. For 12 months you can use Tula to access information, strategies, and resources to understand your health and alcohol

use. During that time, we also ask you to complete a series of surveys related to your health and wellness, quality of life, progress and goals towards new positive habits, and alcohol use. You do not have to answer any questions that make you feel uncomfortable. You will be paid for every survey completed (up to $250 total). There are no costs to you.

- **What are the benefits and risks?**
  A benefit from being in this study is that you may build healthy habits and reduce your drinking. A second benefit is that findings from this study may help others in the future as we learn more about minimizing the risks associated with alcohol use. The biggest risk is that your information could become known to someone not involved in this study, but we have very strict rules to protect your identity and your PHI. For a list of other risks, see the full Informed Consent, below.

- **What if I have questions?**
  Whether or not you participate in the study will not affect your health care. There are no penalties to withdraw from the study after you start. Once you withdraw, we will not collect new data but may use data already collected. For any questions about the study, contact Christine Stephenson (Program Manager) at 608-263-4492 or Andrew Quanbeck (Lead Researcher) at 608-262-7385. If you have questions about your rights as a research subject or complaints about the study or study team, contact UW Health Patient Relations at 608-263-8009.

Full Informed Consent:

Invitation

The Implementation Science and Engineering Lab at the University of Wisconsin—Madison, Department of Family Medicine and Public Health invites you to take part in a research study about using mobile health (mHealth) technology to support individuals who would like to reduce their alcohol consumption. We are inviting you because you have expressed an interest in participating in this research study AND would like to reduce your alcohol use and build lasting, healthy habits. Based on your completion of the study's web-based screening survey, you are eligible to participate in this study if you so choose.

The purpose of this consent and authorization form is to give you the information you need to decide whether to participate in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Before making a decision, you may ask questions about anything in this form that is not clear by contacting the study team program manager, Christine Stephenson (cstephenson@wisc.edu; (608) 263-4492). If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Please note, you are under no obligation to participate in this study, and you may withdraw from this study at any time—even after you have given your consent. Once you consent to participate in the study, a copy of your signed consent document will be available to you via the

smartphone app you will be using for the study for you to refer back to at any time. You may also email the consent document to yourself for your records.

Why are researchers doing this study?

The purpose of this research study is to see if a smartphone app called "Tula" can help people reduce their drinking and improve their health and quality of life. Tula is a Sanskrit word that means "balance." The study also hopes to discover how this app can be used effectively in primary care.

We are doing this research because alcohol consumption has been shown to affect physical and mental health, quality of life, and overall wellness. The prevalence of drinking in the United States suggests that drinking comprises a broad spectrum of patterns and behaviors ranging from low-risk alcohol use to severe abuse or dependence. Efforts to reduce the risks associated with alcohol use is a public health priority. Government agencies have developed guidelines for moderate drinking and definitions for high-risk drinking patterns, such as binge drinking and heavy alcohol use. Health experts have developed formal criteria for Alcohol Use Disorder, a chronic health condition.

This study is being done at the University of Wisconsin-Madison, in cooperation with the UW Health Center for Wellness at the American Center, Safe Communities of Madison–Dane County, and UW Health clinics. It is expected that a total of 546 people will participate in this study.

Funding for this study is provided by the National Institute on Alcohol Abuse and Alcoholism of the National Institutes of Health under Award Number R01AA024150. A description of this clinical trial is available at http://www.ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT04011644) 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.

What will happen in this study?

If you decide to participate in this research study, the researchers will ask you to use the Tula app and complete the activities described below.

PHASE I: ONBOARDING
During the initial phase of your participation, the research team will ask you to complete a series of in-app activities designed to confirm your eligibility, set-up the app so you can participate in the study, and provide baseline data for the research team. You will have access to a Quick Start checklist in the app to guide you through the process, which will include the following:

> *Create an Account.* Immediately after completing and digitally signing this informed consent agreement, you will be asked to create a Tula account. Account set-up will involve entering your first and last name, entering your email address, and creating a username (alias) and password. To protect your privacy, please do not use your real name as your username; we also ask that you do not include telephone numbers, zip

codes, birthdates, or other confidential information when choosing a username.

After creating your account, you will have 72 hours to complete the following items in the Quick Start checklist:

Baseline Survey. The baseline survey establishes a foundation of information that will allow the researchers to measure what changes, if any, you experience over the course of your participation in this study. This survey will collect general demographic information, and you will be asked questions about the amount of alcohol you drink; your activities, interests, and relationships with others; and your health and wellbeing. You may skip any question(s) on the baseline survey that you do not want to answer. We estimate that it will take you approximately 5 minutes to complete the baseline survey.

What Matters to You Survey. This short-answer survey asks you to describe why your health is important to you and to think about what motivates you to do good things for yourself. Your answers will not be shared with the study team; as a feature of Tula, the purpose of this survey is to help you put your thoughts about your health and wellness into words. You may choose whether to share your answers with others, even when, later in the study, you may be given the option to do so.

Set Your Goals. As a starting point for your participation, we'll ask you to set goals related to your alcohol use, your health, and your wellbeing. Your goals will not be shared with members of the study team or other participants unless you choose to share them. You will be prompted to revisit your goals each week for the first 12 weeks you are enrolled in the study, and you may return to these goals at any time.

The app will send you a reminder to complete the elements of the Quick Start checklist 48 hours after you download it. When you have completed all of the items on the Quick Start checklist, a member of the research team will contact you, using the email address you provide when you create your Tula account, to schedule a brief phone call to confirm that you are eligible and that you want to participate in the study. During that call, you may ask additional questions about the study. Once all your questions have been answered and you confirm your consent to participate, the study team member will assign you, at random, to one of three groups: (1) an app-only group, where participants will use Tula on their own; (2) a group whose use of Tula includes access to an in-app discussion forum, a private messaging platform, and the support of peer mentors; or (3) a group whose use of Tula is guided by a health coach from the UW Health Center for Wellness at the American Center and enables in-app communication with the health coach and other research participants via the Tula discussion forum and private messaging platform; participants in this group will also have the option of scheduling up to three sessions, either in-person or via phone call, with a health coach.

Once you are randomly assigned to one of the three groups described above, you will receive a second, brief digital consent form detailing what your participation in that group will entail. If you consent, your enrollment in the study will be complete. If you do not consent, the study team will only retain a record of your age, biological sex, and race/ethnicity; all other information you have provided—including your name, username, and contact information—will be destroyed.

PHASE II: ACTIVE PARTICIPATION

While some study activities will vary from group to group, all participants will be asked to provide the following:

App use data. Tula includes a collection of features, tools, and resources that you may use to learn about alcohol use, health, and wellness; track your progress toward your goals; note your thoughts and experiences; build new, positive habits, etc. Because we are interested in how people will use these features, with your permission, the app will collect use data by placing "cookies" on your smartphone. Data are stored on a secure central server at UW-Madison's Center for Health Enhancement Systems Studies and will be available to the research team for the purpose of analysis. The data we collect may include time-stamped log files that record when you accessed the app, the services selected, duration of use, pages viewed, and the frequency of messages posted and received

Survey data. Throughout your participation in this study, we will ask that you use the Tula app to complete a series of brief surveys related to your alcohol use, your quality of life, your progress and goals, and other questions related to your general health and wellness. Some survey questions will ask you about depression. In the context of the study, these survey questions are not intended to diagnose depression; however, should your responses signal to the research team that you might be struggling, the program manager and/or one of the study physicians will initiate follow-up with you via Tula's private messaging platform. The brief surveys will include the following:

Weekly surveys (12). Each week for the first 12 weeks of your participation in the study, you will use the app to complete a brief survey, which asks you to recall your use of alcohol for the past 7 days and rate your well-being and quality of life for the same span of time.

Quarterly surveys (4). At months 3, 6, 9, and 12 you will be asked to complete a more comprehensive survey about your alcohol use, habits and behaviors, overall health and wellness, use of medical services, and quality of life. You'll also be invited to reflect on and share your experience related to your use of the app. Though more comprehensive than the weekly surveys, we estimate that the quarterly surveys should take approximately 5 minutes or less to complete.

You may skip any question on any survey that you do not wish to answer.

How long will I be in this study?

You will be a part of the study for 12 months. The first 3 months (12 weeks) will involve weekly surveys, as noted above. In the 9 months that follow, you may continue to use Tula as much or as little as you want. The research team will ask you to complete a research survey, via the app, every 3 months to follow up with you about your experience, though you have no obligation to continue to use Tula.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will collect your name, date of birth, home address, phone number, email address, race, ethnicity, education, marital status, alcohol use, and how you are feeling physically and mentally, which involves the following kinds of PHI:

- Data collected as part of the study (i.e. your survey answers)
- Things you tell the research team about your health, through your use of the app, or through communication with members of the research team

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely.

The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

A list of participants' usernames will be kept by the research team's principal investigator and stored in a password-protected spreadsheet. This data will be kept in a secure, limited access, password-protected file service on secure servers located within the Health Innovation Program at the University of Wisconsin--Madison. Any hard copies of records containing identifying information will be stored in a locked file cabinet. Other identifiable data you share via the app will be removed by the research team's data security officer and confirmed by the University's honest broker before it can be accessed by the research team

However, we cannot promise complete confidentiality. Federal or state laws may require us to show information to university or government officials and study sponsors responsible for monitoring the safety of this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts). In cases of imminent threat of harm to others, staff would call 911.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule calls with participants, handle accounting and distribute incentives, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, The National Institute on Alcohol Abuse and Alcoholism, as part of the U.S. National Institutes of Health
- Collaborating researchers outside UW-Madison, including researchers at the University of Kentucky
- Companies or groups performing services for the research study, such as Safe Communities of Madison—Dane County

Will information from this study go in my medical record?

None of the information we collect for this study will go in your medical record. The researchers are not required to release health information to you if it is not part of your medical record.

How is being in this study different from my regular health care?

This study is not part of your existing regular health care, but if you are concerned about or would like to learn more about your risks associated with alcohol use, you have many options. It is always advisable to meet with your primary care provider to have a conversation to decide whether to screen for risky drinking or alcohol use disorder. Your primary care provider can also recommend resources to help you reduce your drinking, regardless of your motivation for doing so. If you participate in this study, you may continue to seek care or pursue treatment as you normally would.

In this study, you will have access to information, strategies, resources, and decision-making tools to help better understand your health related to alcohol use. Tula offers these tools to guide conversations about your health. You may also have access to communities and health care professionals who can support you as you learn how to change your habits. The surveys you complete will help the study team understand how useful these strategies and resources are to you.

Please note, however, that Tula is itself is not a diagnostic tool; it will not deliver a clinical diagnosis, and is not a treatment plan. There is no substitute for seeking care from your trusted health professionals.

Will being in this study help me in any way?

Being in this study may help you reduce your drinking and build healthy habits. However, we cannot promise these things will happen. Even if the study does not help you directly, your participation in the study may help other people in the future by helping us learn more about minimizing the risks associated with alcohol use.

What are the risks?

- There is a risk that your information could become known to someone not involved in this study.
- If your smartphone is lost or stolen, any personal information that you have put on the phone could be seen by unknown others. We recommend protecting your phone with a passcode to lessen this risk.

- Tula could give you inaccurate information. However, we (the research team) carefully review and verify the information before putting it in the app, so this is unlikely.
- You could receive inaccurate information from the internet. Links to internet sites provided in the app are also carefully reviewed by the research team before they are included in the app, but we cannot anticipate edits or changes the owners of that content make.
- There is a risk that information you disclose could become known to someone not involved in this study, though you will always have the final say about what information you choose to disclose and whether to communicate with members of the research team.
- Information in the app and responding to surveys in Tula could cause you to feel anxiety, distress, embarrassment, or sadness. You never have to answer any questions that you do not want to answer.
- We may discover thoughts or behavior that raise concerns about your harming yourself or others. If we see anything that suggests that you or others face imminent risk of harm, we will contact appropriate others to intervene (e.g., the police). We are required by law to report suspected child abuse and will do so if the issue arises during the course of the study.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

If you decide to be in the study, the researchers will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Please let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health, or any affiliated organizations, nor will it affect any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to access your protected health information (PHI) will last until the research study is done. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.

- To take back your authorization, please write to Principal Investigator Andrew Quanbeck at arquanbe@wisc.edu or at 800 University Bay Drive, Suite 210 53715 Madison, WI.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care and support for reducing your alcohol use. If you decide not to take part in the study, you have other choices. For example:

- you may choose to get the regular care described above
- you may seek support from public health communities dedicated to supporting alcohol-related health concerns
- you may contact a clinic that specializes in providing alcohol use treatment
- you may choose to take part in a different study, if one is available

Will being in this study cost me anything?

There will be no cost to you for downloading and using the Tula app, interacting with the study staff, peer mentors, or health coach. We do ask that you use your personal cell phone and plan, so some data rates may apply. We intend the stipends for participation (see below) will help offset any data/mobile phone costs associated with participation in the study.

Will I be paid or receive anything for being in this study?

If you complete all requested data collection over 12 months, you will receive up to $250 for being in this study. We will pay you up to $30 for taking a baseline survey; $10 per weekly survey completed for 12 weeks ($120 total); $20 for 4 surveys taking place at 3, 6, 9, and 12 months; and a bonus $20 for completing all surveys over the 12 months. Payment will be provided at the end of each month. You may choose to be paid by check, mailed to the physical address you provide, or by digital gift card delivered via email. If you choose to leave the study early, you will receive the amount equal to the number of surveys completed.

What if I have questions?

If you have questions about this research or you feel you have been harmed by participating in this study, please contact the Program Manager, Christine Stephenson, at (608) 263-4492 or the Principal Investigator, Andrew Quanbeck, at (608) 609-7308. If you have any questions about your rights as a research subject, have complaints about the research study or study team, contact UW Health Patient Relations at (608) 263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Agreement to participate in the research study

You do not have to digitally sign this form. If you choose not to sign, however, you cannot take part in this research study.

If you check the box and fill in your name below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered any questions you had.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Step 1. Check the box below

By checking this box and typing my name below, I am electronically signing my application.

Step 2. Type in your name

First name:

☐ Middle initial:

☐ Last name:

☐ Suffix:

****A copy of this form will be available to you under "Study Information" in the app.****