

UNIVERSITY OF WISCONSIN-MADISON

**Subject CONSENT to Participate in Research
And
AUTHORIZATION to Use and/or Disclose Identifiable Health Information for
Research**

Title of the Study: Building and pilot testing a couples-based smartphone system to address alcohol use disorder

Principal Investigator:

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INVITATION

You are invited to participate in a research study to develop and pilot test a new smartphone-based support system for Alcohol Use Disorder (AUD) patients and their partners called PartnerCHESS. PartnerCHESS will add key features of Alcohol Behavioral Couples Therapy (ABCT) to a smartphone-based support system that is currently available for clinical use called A-CHESS (Addiction CHESS). ABCT is an outpatient treatment for individuals with an alcohol use disorder, which includes their intimate partners in the treatment program. A-CHESS is a relapse-prevention program provided through a smartphone application.

You are invited to take part because you have been diagnosed with AUD or meet NIAAA guidelines for high-risk drinking. Approximately 34 individuals and their partners will take part in this study.

Your participation in this research study is voluntary. If you decide not to participate, the health care provided to you will not be affected in any way.

Funding for this study is provided by the National Institutes of Health.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research is to develop and test PartnerCHESS. In addition, we will see, for patients with AUD, if there is a difference in number of risky drinking days, quality of life, and use of health care services, for those who receive the smartphone application A-CHESS and treatment as usual (TAU) or the newly developed PartnerCHESS and TAU.

WHAT WILL MY PARTICIPATION INVOLVE?

If you decide to participate in this research you and your partner will be randomly assigned by chance (similar to flipping a coin) to one of two groups. Because it is random, we cannot guarantee which group you will be in.

The groups you could be assigned to are:

- 1) A-CHESS + TAU
- 2) PartnerCHESS + TAU

If you are assigned to the A-CHESS group, you will be given access to the A-CHESS Smartphone Support System to use during the study.

If you are assigned to the PartnerCHESS group, you and your partner will be given access to the new PartnerCHESS Smartphone Support System to use during the study.

Regardless of which group you are in, you and your partner will complete four surveys during the study. The surveys will be done over the phone with a research study coordinator at enrollment, 2 months, 4 months, and 6 months. These surveys will take about 45 minutes to complete and will ask you information about your health, your drug and alcohol use, and how you are feeling.

A-CHESS and PartnerCHESS Activities:

The following are activities that you will complete using the smartphone application system. These activities are the same whether you are assigned to the A-CHESS or PartnerCHESS Group.

1. Self-directed, interactive modules that teach basic recovery support skills such as refusing drugs and managing thoughts about drug use. Additional modules teach skills to improve psychosocial functioning (family/social relations, managing negative moods, etc).
2. Monitoring prompts, peer and family support, information about addiction and recovery support, and resources on where you can go for help with your recovery.
3. A way to talk with other study participants without ever needing to share your name or seeing them. This is done by sending messages through the A-CHESS/PartnerCHESS online discussion group. Your partner will not have access to this discussion group and you will not have access to the partner-only discussion group.
4. Automated analysis of the public discussion group messages that allow for tailored feedback and resources to be sent to you through the app.
5. You will be asked to complete weekly check-ins on A-CHESS or PartnerCHESS that will ask questions about how you are doing, your alcohol and drug use, and your confidence in your recovery. These questions will be sent to you through the smartphone application and will take about 2-4 minutes to complete. All questions are voluntary. You are free to refuse to answer any survey questions you are uncomfortable with.

As we are trying to understand if and how a substance recovery system might help people, we will also track which features of the A-CHESS or PartnerCHESS system you use. A-CHESS/PartnerCHESS can use GPS to monitor your location and help support your recovery. You can identify locations, like a bar or restaurant, that you consider “risky” to your recovery. If you are physically near one of those locations A-CHESS/PartnerCHESS can send you an alert using your phone’s notification system. You are not required to use this feature - you can turn it off if you choose not to use it.

PartnerCHESS ONLY Group

PartnerCHESS includes all of the features of A-CHESS along with elements of Alcohol Behavioral Couples Therapy (ABCT) such as a relapse plan, reminders, and trigger identification. Your partner will receive PartnerCHESS and if necessary, a smartphone. Your partner will be completing the weekly check-ins, potentially using tools outlined above as well as using the ABCT components.

Your participation in this study will not have a negative or positive effect on the health care you receive from your provider and it will not have a negative or positive effect on your legal situation if you are on probation or parole. The researchers will not be reporting to your probation/parole office or board. However, we encourage you not to discuss any illicit or illegal behavior on the A-CHESS or PartnerCHESS.

How we will use your protected health information (PHI)

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 use the following kinds of PHI:

- Information you provide using A-CHESS or PartnerCHESS as part of the study
- Things you tell the researchers about your health including from surveys

HOW LONG WILL I BE IN THIS STUDY?

You will be part of the study for 6 months. If you decide to participate in this study, certain situations may occur during your 6-month study period. Below are 3 common scenarios and details on the process that would be followed if you are in one of these situations.

1. If you are unreachable for follow-up surveys your study phone service would be discontinued if applicable.
2. If you are incarcerated, no research activities would occur during the time of incarceration. You can contact the UW study coordinator if you are released during the original study period if you would like to continue on study.
3. If you and your partner separate, one or both of you can continue in the study if you wish. You can of course, at any time, choose to no longer participate.

The researchers may also take you out of the study, even if you want to continue, if you use the phone in an inappropriate manner (i.e. messages including nudity, threats, racism, bigotry), research staff will delete the inappropriate messages and follow up with you. If the behavior continues, research staff may decide to withdraw you from the study without your consent for your best interest as well as others on the study.

HOW IS BEING IN THIS STUDY DIFFERENT FROM MY REGULAR HEALTH CARE?

If you take part in this study, the main difference between your regular care and the study is the use of the A-CHESS or PartnerCHESS application to aid in your treatment.

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 for your Alcohol Use Disorder. If you decide not to take part in the study, you have other choices including seeking treatment in your area.

ARE THERE ANY BENEFITS TO ME?

Your taking part in this research is not expected to benefit you directly, but it may benefit other people in the future by helping us learn more about how a smartphone with a recovery support system can improve patient quality of life and improve the health care given to others with substance abuse problems.

WILL I BE PAID FOR MY PARTICIPATION?

You will be paid \$20 for each survey you complete. The total you will be paid if you complete all of the surveys is \$80.

If you have a smartphone, we will download the PartnerCHESS or AChess app onto your phone and you will be paid \$50/month towards your phone service for 6 months. The total you will be paid towards your phone service is \$300.

If you do not have a smartphone, you will be given one and the study will pay for 6 months of phone service.

WHAT HAPPENS TO THE SMARTPHONE AFTER THE STUDY?

If you receive a study smartphone, you will be able to keep the smartphone at the end of the study if you complete all of the surveys. However, after 6 months, the study will no longer pay for the monthly service plan on the smartphone.

ARE THERE ANY COSTS?

There are no costs to you to join this study. There are no costs to use the study smartphone for personal use or to search the internet. There are no costs to you if the smartphone is lost or stolen.

WHAT ARE THE RISKS TO ME?

You could get wrong information from A-CHESS, PartnerCHESS, or other participants in the study. However, a panel of experts in the field of addiction looks at all information before it is put on the smartphone and research staff moderate all discussion group messages so this risk is unlikely.

Reporting on sensitive issues (such as drug and alcohol use and mental health) while using the A-CHESS or PartnerCHESS recovery support program may cause anxiety, distress, embarrassment, or feelings of sadness. However, you do not have to answer any questions that you do not want to answer.

There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job. The steps we will take to protect your confidentiality are described below.

Different activities you participate in during this study may show that you are experiencing symptoms of emotional distress such as depression, thoughts of self-harm or harm to others. If any study activities show that you are experiencing emotional distress, we may reach out to you to assist you in getting the help you need. This may include directing you to community resources or connecting you with support directly, such as a member of your medical team. In rare instances this may include contacting emergency services to assist you.

If potential harm to others is identified, then it may be necessary for us to contact local authorities to ensure your protection or the protection of others. As researchers, we are also required to report child abuse to the authorities and will do so if the issue arises during the course of this research.

The A-CHESS and PartnerCHESS systems allow you to share your views, opinions, photos and personal experiences to aid in your recovery. However, you do not have the right to post content on A-CHESS or PartnerCHESS that promotes racism, bigotry, hatred, nudity or physical harm of any kind against any group or individual. A research staff member will review and delete any messages deemed inappropriate. A research staff member will then follow up with the author of the inappropriate content. If the behavior continues, research staff may decide to withdraw you from the study for your best interest as well as others on the study.

Information posted on A-CHESS or Partner-CHESS that suggests potential involvement in illegal activities may be reported to local authorities, such as the police.

If your smartphone is lost or stolen, we will not be able to replace it. You may feel some loss if this occurs. Also, any personal information that you've put on the phone could be seen by unknown others.

If the study provides you a smartphone, the service for the smartphone is stopped after 6 months from the date you enrolled in the study. You may feel some loss when you no longer have that service.

Email communication with the study team is not required. However, if you choose to email the study team, be aware that email is generally not a secure way to

communicate about your health or other sensitive issues as there are many ways for unauthorized users to access email.

HOW WILL THE 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 health information, your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and to study sponsors responsible for monitoring this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities if abuse is identified or if there are concerns that you may harm yourself or others.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, the National Institutes of Health
- Collaborating researchers outside UW-Madison, including researchers at the University of Massachusetts.

Will information from this study go in my medical record?

None of the information that is collected from the surveys you complete or your use of PartnerCHESS (if you are assigned to that group) will be placed in your medical record. Authorizing the research team to use your PHI means that we can release it only to the people or groups listed above, and only for the purposes described in this form. However, 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, if ALL information that can identify you is removed from the health information collected in this study, then it is no longer PHI and this authorization will no longer limit how the remaining information can be used. This means the information could be used or shared for reasons other than the ones described in this form, such as a research study about another kind of disease. It also means that the information could be shared with researchers working at institutions that are not listed above.

A description of this clinical trial will be available on <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.

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.

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 or any relationship you might have with the University of Wisconsin-Madison. 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 use your protected health information (PHI) does not have an end date. 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, you will need to tell the researchers by writing to the Principal Investigator, David H. Gustafson, Ph.D., at the University of WI-Madison, Industrial Engineering, 1513 University Ave., Mechanical Engineering Building, Room 4109, Madison, WI 53706.

DISCLOSURE OF FINANCIAL INTERESTS

Members of this research team at the University of Wisconsin-Madison have a personal interest in or might profit financially from the results of this study. This is called a “conflict of interest.” Members of the research team have an ownership interest in CHESS Mobile Health, Inc., which owns and licenses the A-CHESS and PartnerCHESS applications being used in the study. The conflict of interest may affect whether you want to take part in this study.

The University of Wisconsin-Madison has rules to manage conflicts of interest that help protect study participants and the quality of the data collected. One way UW-Madison manages conflicts is to limit the role that a researcher with a conflict can have on a study, such as not allowing a person with a conflict to obtain informed consent or recruit potential subjects.

Researchers may develop products from the information you provide for this study. Some of these products may have commercial value. If the research team or others use your information to develop products of commercial value, you will not receive any profits from products created from your information.

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

Please take as much time as you need to think over whether or not you wish to participate. If you have any questions about this study at any time, contact the Principal Investigator David H Gustafson, PhD. at 608-263-4882. You can also contact the Project Coordinator, Dave Gustafson Jr. at 1-800-361-5481.

If you have any questions about your rights as a research subject or 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.

YOU WILL BE ASKED TO VERBALLY CONSENT TO THE FOLLOWING STATEMENT DURING YOUR FIRST STUDY SESSION OVER THE PHONE WITH A STUDY COORDINATOR:

I have read this consent and authorization form. It describes the research study procedures, risks, and benefits of being in the study. It also describes what and how my health information will be used. I have had a chance to ask questions about the research study, including the use of my health information, and I have received answers to my questions. I agree to participate in this research study, and permit the researcher to use and share my health information as described above. I understand that subject anonymity and data confidentiality cannot be maintained if A-CHESS or Partner-CHESS finds evidence of abuse, suicidality, or criminal activity.

Please keep this consent form for your reference.