Family-focused vs. Drinker-focused Smartphone Interventions to Reduce Drinking-related Consequences of COVID-19

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Partner Informed Consent Document Date: March 30, 2022

UNIVERSITY OF WISCONSIN-MADISON

Study ID: 2021-0943
Principal Investigator: David H Gustafson, Ph.D. (608) 262-3768

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

Title of the Study: Family-focused vs. Drinker-focused Smartphone Interventions to Reduce Drinking-related Consequences of COVID-19

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INVITATION
You are invited to participate in a research study to develop and test a new smartphone-based support system for Alcohol Use Disorder (AUD) patients and their family partners called PartnerCHESS-C. PartnerCHESS-C combines services from a smartphone-based relapse-prevention program with COVID resources and content to address comorbid use of other drugs (ACHESS-C) and key features of Alcohol Behavioral Couples Therapy (ABCT), an outpatient treatment for individuals with an alcohol use disorder, which includes their partners in the treatment program.

You are invited to take part because your family partner has Alcohol-use Disorder (AUD) or meet National Institute on Alcohol Abuse and Alcoholism (NIAAA) guidelines for high-risk drinking. Approximately 198 individuals and their family 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-C. In addition, we will see, for patients with AUD, if there is a difference in number of risky drinking days, quality of life, and relationship satisfaction for those in the smartphone control and ACHESS-C groups versus the newly developed PartnerCHESS-C.

WHAT ARE SOME REASONS I MIGHT–OR MIGHT NOT –WANT TO BE IN THIS STUDY?

You may want to be in this study if you are:	You may NOT want to be in this study if you:
• Comfortable having researchers ask questions about your and your family partners' drug and alcohol use and mental health. • Willing to participate in the study for 12 months. • Interested in contributing to scientific knowledge even though you won't benefit directly from the study.	• May not have time to complete study questionnaires. • Are uncomfortable having researchers ask questions about your and your family partners' drug and alcohol use and mental health.

WHAT WILL MY PARTICIPATION INVOLVE?

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

The groups you could be assigned to are:

1) ACHESS-C: you and your family partner will receive a smartphone, if you don't already have one, with contact information for standard AUD, SUD, and crisis support (e.g. AA, NA, Al-Anon). Your partner will receive the ACHESS-C app.
2) PartnerCHESS-C: you and your family partner will receive a smartphone, if you don't already have one, with the PartnerCHESS-C app.
3) Smartphone Control: you and your family partner will receive a smartphone, if you don't already have one, with contact information for standard AUD, SUD, and crisis support.

Regardless of which group you are in, you and your family partner will complete four surveys during the study. The surveys will be done over the phone with a research study coordinator at enrollment, 4 months, 8 months, and 12 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.

PartnerCHESS-C Group:

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

The following are activities that you will complete using the PartnerCHESS-C smartphone application.

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 partner's 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 PartnerCHESS-C online discussion group. Your partner will not have access to this discussion group and you will not have access to the patient-only discussion group.

4. You will be asked to complete weekly check-ins on PartnerCHESS-C 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 PartnerCHESS-C system you use. This includes which features are used and discussion group messages.

PartnerCHESS-C also includes elements of Alcohol Behavioral Couples Therapy (ABCT) such as a relapse plan, reminders, and trigger identification. Your family partner will also receive PartnerCHESS-C and will be completing the weekly check-ins, potentially using tools outlined above as well as using the ABCT components.

ACHESS-C and Smartphone Control Group

If you are assigned to the ACHESS-C or smartphone control group, you will only need to complete the 4 surveys over 12 months. You will receive contact information for standard AUD, SUD, and crisis support (e.g. AA, NA, Al-Anon) and a smartphone if you don't have one. Your partner will be given access to the ACHESS-C Smartphone Support System to use during the study, which includes access to the resources listed in points 1-4 above.

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 PartnerCHESS-C app.

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 PartnerCHESS-C 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 12 months. If you decide to participate in this study, certain situations may occur during your 12-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 PartnerCHESS-C 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 for your partner to get care for Alcohol Use Disorder or to take part in family therapy. If you decide not to take part in the study, you have other choices including seeking treatment for your partner or yourself in your area.

ARE THERE ANY BENEFITS TO ME?
A potential benefit may be a reduction in heavy drinking days for your family partner and improvement in quality of life for you and your family partner.

Although takingpart in this research may not benefit you directly, it may benefit other people in the future by helping us learn more about how a smartphone witha recovery support system can improve patient and family partner 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 $25 for each survey you complete. The total you will be paid if you complete all of the surveys is $100.

If you have a smartphone and are in the PartnerCHESS-C group, we will download the PartnerCHESS-C app on to your phone and you will be paid $50/month towards your phone service for 8 months.The total you will be paid towards your phone service is

$400.

If you do not have a smartphone, you will be given one and the study will pay for 8 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 8 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. If you use your own smartphone during the study, CHESS will pay you $50 per month to put toward the cost of your personal cellular plan. Depending on the cost of your cellular plan, the $50 may not cover the entire monthly charge. You would be responsible for paying any amount over $50.

WHAT ARE THE RISKS TO ME?
You could get wrong information from PartnerCHESS-C 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 PartnerCHESS-C 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.

If it is found that one treatment arm is more effective than another treatment arm, there is a potential for less effective results for those randomized to the less effective arm.

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. In addition, as researchers, we may be required to report or voluntarily report child abuse to the

authorities if the issue arises during the course of this research. Some states have laws requiring or permitting reporting of substance abuse during pregnancy, and if those laws apply, we may be required to report or voluntarily report such information to the appropriate authorities. It is also possible that other users of the app may report substance abuse during pregnancy or other information shared in the app. Participants in this study are not required or expected to share information about pregnancy status in ACHESS-C or PartnerCHESS-C.

The PartnerCHESS-C systems allow you to share your views, opinions, photos and personal experiences to aid in your recovery. However, you do not have theright to post content on PartnerCHESS-C 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.

While we will follow the above procedures to remove offensive content, there is the potential of seeing offensive content, posted by other study participants, on ACHESS-C or PartnerCHESS-C, before staff members can remove it.

Information posted on PartnerCHESS-C 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 after8 months from the date you enrolled in the study. You may feel some loss when you no longer have that service.

Permission to communicate about the study by email
We are requesting your email addressto use as a back-up contact. If we are unable to reach you by phone to schedule and conduct surveys, we may email you. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Dave Gustafson, Jr, Study Coordinator at 608-520-6322.You do not have to provide your email address to participate in this study.

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-C (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.

WILL I RECEIVE THE RESULTS OF RESEARCH TESTS?
The questionnaires you will complete in this study ask about symptoms of emotional distress such as anxiety. We are using the questionnaires only for research, not to diagnose mental health issues. We will not tell you the results. If you are experiencing emotional distress, you should contact your physician or other health care provider, such as a mental health professional.

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, write tothe 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 ACHESS-C and PartnerCHESS-C 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 recruitpotential 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.

WHAT WILL HAPPEN TO MY DATA AFTER MY PARTICIPATION ENDS?

We will keep your data for an indefinite period of time, meaning we have no plans of ever destroying it. Keeping data for future research is called "banking." The banked data will be kept in a secure location for use by researchers.

We will use the data in future research projects about eHealth interventions' impact on substance use disorder. We may also use them for other types of research. The data may be shared with other researchers at the University of Wisconsin-Madison and outside the University. Outside researchers may be at other universities, private companies, or other kinds of organizations. Banked data will not be shared with your health care providers or used in your treatment outside this study.

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 answersto 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 or PartnerCHESS-C finds evidence of abuse, suicidality, or criminal activity.

Please keep this consent form for your reference.