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Approval Date: September 15, 2021
Expiration Date: September 15, 2022

STANFORD UNIVERSITY
CONSENT TO PARTICIPATE IN A RESEARCH STUDY with HIPAA

Study Title: Pilot Study: Digitally Delivered Intervention for Reducing Problematic Substance Use

Are you participating in any other research studies? _____ Yes _____No

You are invited to participate in a research study being conducted by Dr. Judith Prochaska, PhD, MPH and her colleagues at the Stanford Prevention Research Center in the Stanford University Department of Medicine. Participation in this study is voluntary. The purpose of the study is to test a new digitally delivered intervention compared to another digitally delivered intervention in reducing problematic substance use.

After the baseline (first) survey, you will be asked to participate in a remote (phone or video) interview focusing on your substance use. Then, you will participate in an 8-week program that will include substance use content delivered through a digital interface. Halfway through the program and at the end of the program, you will be asked to complete questionnaires related to the program. You will be asked to provide a blood sample after the baseline assessment and after you complete the program. The blood sample collection can be completed at home. Sample collection involves pricking your finger, leaving small spots of blood on a card, and mailing the card back to us. This test will be used to measure alcohol levels in the blood.

The risk of participation is minor and include possible discomfort in answering sensitive questions and the potential for health information to be leaked. The research team takes serious steps to minimize the chance that these possible risks occur. You may also experience discomfort when pricking your finger to provide blood samples.

You may benefit from participation by gaining awareness of your substance use and potentially reducing your substance use, although we do not guarantee that you will benefit from participating. Alternative treatments to this study include in-person individual and group forms of psychotherapy as well as Alcoholics Anonymous and Narcotics Anonymous.

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PURPOSE OF THE RESEARCH

The purpose of this research is to learn whether a new, digitally delivered program helps to reduce substance use more effectively than a digitally delivered standard intervention. You were selected as a possible participant in this study because you use a smartphone, are between 18-65 years old, and have a substance use concern. The digitally delivered program being studied is not an approved treatment by the Food and Drug Administration (FDA).

If you decide to terminate your participation in this study, you should notify Dr. Judith Prochaska at (650) 724-3608, or email surveys4health@stanford.edu.

In this pilot study, we are looking for 20 people to interact with an intervention so we can further develop our study procedures.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now and withdraw your consent later to stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

Your participation in this research study is expected to take approximately three months (12 weeks). The program will take 8 weeks to complete, with questionnaires at the beginning, at mid-intervention (4 weeks in), at the end of the intervention (8 weeks since starting), and a follow-up questionnaire around 12 weeks after beginning the program. Each questionnaire set (first survey, 4-week survey, 8-week survey, 12-week survey) may take 15-30 minutes. There is a remote interview after the first survey. You will be asked to complete dried blood spot tests after the first survey and after the 8-week survey.

Baseline Assessment

- Online survey (estimated 15-30 min)
- Phone/video interview (estimated 30 min – 1 hour)
- PEth test (can take up to 30 min)

Mid-Intervention (4-week) Assessment

- Online survey (estimated 15-30 min)

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End of Treatment (8-week) Assessment

- Online survey (estimated 15-30 min)
- PEth test (can take up to 30 min)

30 Days after End of Treatment (12-week) Assessment

- Online survey (estimated 15-30 min)

PROCEDURES

If you choose to participate, you will complete the baseline survey (first survey). After the baseline survey, you will be asked to schedule an interview (phone or video). The interview will focus on your substance use. After the interview, you will be assigned at random, with 50% chance, into one of two digitally delivered substance use interventions. You will not be told which digitally delivered substance use intervention (new vs standard) you are assigned to. This is to test the effectiveness of the intervention without being influenced by what one may think or hope might happen. The details of what your intervention group will involve will be provided after randomization occurs. At the end of the study, you will be provided with information about what the two groups involved.

For both groups, the intervention involves an 8-week program that will include content delivered to you digitally. Each piece of content will take approximately 10 minutes to go through. For one group, the intervention content is accessible for only the 8-week period.

Surveys: You will be asked to complete a total of four questionnaires: one at the beginning of the 8-week program, one at the 4-week mark, one at the end of the 8-week program, and one 30 days after the program ends (approximately 12 weeks since starting). You have the right to refuse to answer particular questions.

PEth test: You will also be asked to complete a dried blood spot test within 3 days after completing the baseline assessment, and after completing the end of treatment survey. This test, called a PEth test, measures changes of alcohol content in the blood over time. The research team would like the timing of the PEth tests to align with your baseline and end of treatment surveys. Only your study ID number will be associated with your tests. Your identifying information will NOT be on your PEth tests. A test will be mailed to you after the baseline survey, and another before the end of treatment survey. You will be compensated for returning each completed PEth test.

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Why are dried blood spot tests involved?
Survey data can help us determine which program works better. Biological changes, such as changes in markers of alcohol use in your blood, provide additional evidence to tell us whether the new program works or not. The PEth test is one way of measuring biological change over time. The study team is hoping to explore whether the outcomes of the PEth test results show meaningful change over an 8-week period. Results will be informative for future research. Your PEth test results will NOT be tied to your compensation. You will be compensated for returning completed test kits, regardless of the results.

This research hopes to compare differences in substance use outcomes among the two interventions.

Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Use the study program as instructed.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not lose any benefits to which you would otherwise be entitled.

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If you decide to withdraw your consent to participate in this study, you should notify Dr. Judith Prochaska at (650) 724-3608, or email surveys4health@stanford.edu.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The study is cancelled.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The risks of participation include possible discomfort in answering sensitive questions and the potential for health information to be leaked. The responses to questions concerning illegal drug use could be self-incriminating and harmful to you if they became known outside the study. As explained in the confidentiality statement of the consent, we do not intend to disclose this information. The research team takes serious steps to minimize the chance that these possible risks occur. To protect your privacy, the researchers will store data in encrypted and password protected computers and will train staff in how to handle confidential data. It is also possible that the study may involve risks to you, which are currently unforeseeable.

To be identified as part of either study intervention, email address will need to be shared with Woebot, as the intervention programs are designed and managed by them.

As part of this research study, you may be asked to use a Woebot developed program for the duration of active study participation (8-weeks long). Use of the program requires you to agree to its Terms of Service and Privacy Policy. The Privacy Policy explains how the program collects, stores, uses, and shares your personal data. While using this program, data about you including email

address, first name, and program usage information will be collected and transmitted to the Stanford research team and to the Woebot employees. The personal information is collected when you register for the program by creating an account and when you exchange text or messages with the program. While the Privacy Policy states the email component is optional, the study team would need an email address in order to identify you as a participant in the intervention. The information collected by the program is not shared with any other company or service. The program does not access any of your other social media profiles or accounts. Upon completing the final assessment at the 12-week mark, you will be removed from all study applications and programs.

The Terms of Service explain the conditions and limits for using the program. For example, the Terms of Service explain that the program is to be used only for informational and educational purposes. It is to be used as a self-help program that may provide support and feedback to you. The program does not provide medical care, mental health services, or other professional services. If you need care or help that is more than this self-help program can offer, the program will advise you to seek care from a mental health professional, medical professional, or as recommended by the study team.

Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your information. Safeguards are put in place to protect your personal information. Please read the Terms and Service and Privacy Policy, which are separate from this consent form, carefully before deciding whether you agree to use this program. If you decide that you do not want to agree to use the program, then you should not participate in the study.

It is possible that, based on information gained from this study, the researchers may have serious concerns (relating to matters such as severe depression, physical abuse, etc.) about your health and/or safety; in such a case, the researchers may contact you and provide a referral for your care.

The interventions are not intended to replace your current standard of care.

The interventions are not designed for crisis service. However, if there is an indication of a crisis, we will offer resources (9-1-1, suicide crisis hotlines).

The interventions are not designed to treat and manage withdrawal. Certain substances such as alcohol and benzodiazepines can lead to seizures and death if abruptly stopped. Patients with psychiatric or medical co-morbidities may be at a higher risk for complicated withdrawal syndromes requiring closer monitoring

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and treatment. You should consult with your physician before stopping your alcohol use, medications, or substances to determine what level of medical supervision and treatment you need for your withdrawal.

If at any time during the study you develop withdrawal symptoms, you should alert your physician. If you start developing severe symptoms after stopping alcohol, medications, or substances, you should immediately call 9-1-1 for emergency evaluation and/or seek treatment at the nearest emergency department.

If at any time during the study you develop or indicate serious thoughts about suicide or harming yourself, you should immediately call 9-1-1 for emergency psychiatric evaluation and/or seek treatment at the nearest emergency department.

You may be withdrawn from the study if emergency treatment is necessary.

Possible risks, discomforts, and inconveniences with the PEth test include: pain at the puncture site, queasiness with seeing or losing blood, disposal of lancets, and, rarely, infection. Risk of infection is lowered by making sure hands are clean and wiped with the alcohol pad. The sterile lancet should only be used once per test.

If your finger is bleeding heavily, apply pressure to the wound with a clean cloth or gauze, and raise the hand with the bleeding finger above the heart. Keep the pressure on the wound. This will reduce blood flow to the finger and should close up the wound in about a few minutes.

To safely dispose of used and unused lancets, you will be asked to seal the lancets in a hard plastic or hard metal, leak resistant container (for example, coffee tins, empty detergent bottle), label the container as "sharps", and dispose of the container in the landfill trash if allowable in your local area. The lancets can also be taken to a local center that can dispose of the lancets. Please do NOT recap the used lancets.

If you will need a provided container, please let a research team member know and one will be mailed to you.

For more information on sharps disposal and what is allowable in your local area, please visit: https://safeneedledisposal.org/

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POTENTIAL BENEFITS

You may benefit from participation by gaining awareness of your substance use and potentially reducing your substance use.

Results from this study will provide information to help people who have problematic substance use. Society may benefit from a greater understanding of the factors contributing to problematic substance use.

You may benefit from having access to a digitally delivered intervention during a time when healthcare resources are limited and social distancing is encouraged.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

Alternative treatments to this study include in-person individual and group forms of psychotherapy as well as Alcoholics Anonymous and Narcotics Anonymous. All alternative options will be provided if you wish to engage in an alternative treatment rather than the proposed study. No standard treatment is being withheld.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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.

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CONFIDENTIALITY

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the effectiveness of a digitally delivered substance use intervention compared to another digitally delivered substance use intervention; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or specimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring

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the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of as child abuse and neglect, or harm to self or others.

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Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the pilot study?

The purpose of the pilot study is to test a new digitally delivered intervention compared to another digitally delivered intervention in reducing problematic substance use. We will be asking you questions about your health behaviors and personal history, including drug use. Your name will not be used in any published reports from this study. This is a clinical trial so some information in some form will be submitted to the sponsor and the FDA.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that

the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Judith Prochaska, 1265 Welch Road, Stanford, CA 94305-5411.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to, your name, telephone number, geographical information, birthdate, electronic mail address, PEth test results, drug use, IP address, demographic information, and survey/assessment responses, which will also be collected for study purposes.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Judith Prochaska
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff
- Woebot Health

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- National Institutes of Health
- The U.S. Food and Drug Administration (FDA)

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Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2045 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Today's Date

_____
Print Name of Adult Participant

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FINANCIAL CONSIDERATIONS

Payment/Reimbursement
Participants will receive an electronic Amazon gift card after completing each of the following: $10 for the baseline survey, $20 for the MINI interview, $20 for the 4-week survey, $30 for the 8-week survey, and $20 for the 12-week survey. Participants will receive an electronic $25 Amazon gift card for each completed PEth test returned to the study team. Total possible amount of payment per participant is $150.

Payments may only be made to U.S. citizens, resident aliens, and those who are in a status that allows them to receive a taxable payment from a U.S. payer. You may need to provide your social security number to receive payment.

Costs
There is no cost to you for participating in this study.

Sponsor
National Institutes of Health is providing financial support and/or material for this study.

Consultative or Financial Relationships
Dr. Athena Robinson, PhD is Chief Clinical Officer of Woebot Health
Dr. Alison Darcy, PhD, is CEO & Founder of Woebot Health
Sarah Pajarito is a research scientist at Woebot Health
Maddison Pirner is a research assistant at Woebot Health

COMPENSATION FOR RESEARCH-RELATED INJURY

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these

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costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

Due to the coronavirus public health emergency, the federal government has issued a Declaration that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the Declaration applies, it limits your right to sue researchers, healthcare providers, any study sponsor, manufacturer, distributor or any other official involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" please go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650) 723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Judith Prochaska. You may contact her now or later at 1265 Welch Road, Stanford, CA 94305, (650) 724-3608. You should also contact her at any time if you feel you have been hurt by being a part of this study. You can reach a member of the research team by emailing surveys4health@stanford.edu, and at the number (415) 216-5853.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;

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- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Today's Date

_____
Print Name of Adult Participant

Please provide us with the best email for sending communications regarding your participation in this study: _____

Phone number: _____

Mailing address: _____

Participant ID:

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_____ _____
Signature of Person Obtaining Consent Today's Date

_____
Print Name of Person Obtaining Consent

Note: The Person Obtaining Consent section will be filled out by a study staff member and you will be able to access a copy of the signed consent form on the Adobe Sign platform. If you have any questions or concerns, you can reach a team member at surveys4health@stanford.edu or by calling (415) 216-5853.

Participant ID:

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