

Woebot for Substance Use Disorders During COVID-19

NCT04460027

June 19, 2020

STANFORD UNIVERSITY Research Consent Form

Protocol Director: Judith Prochaska, PhD, MPH

Protocol Title: Woebot for Substance Use Disorders during COVID-19

IRB Use Only

Approval Date: June 19, 2020

Expiration Date: May 26, 2021

**STANFORD UNIVERSITY
CONSENT TO PARTICIPATE IN A RESEARCH STUDY with
HIPAA****Study Title:** Woebot for Substance Use Disorders during COVID-19Are 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 program for problematic substance use during COVID-19. This program will be delivered digitally for 8 weeks and will be followed by a questionnaire separate from the mobile application. There will also be a questionnaire at the 4-week mark.

The 8-week program will include daily lessons related to substance use disorder will be delivered through the Woebot mobile application. The assessments will include questionnaires related to the program.

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 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.

PURPOSE OF RESEARCH

The purpose of this research is to learn whether a new, digitally-delivered program helps to reduce substance use during COVID-19. You were selected as a possible participant in this study because you have access to the Woebot mobile application, are between 18-65 years old, and have a substance use concern. Woebot is not an approved treatment by the Food and Drug Administration (FDA).



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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.

This research study is looking for 160 people to use the Woebot mobile application. Stanford University expects to enroll 160 research study participants.

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, but withdraw your consent later and 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 two months. The program will take 8-weeks to complete, and then there will be a questionnaire.

PROCEDURES

If you choose to participate, you will complete the baseline survey (first survey). After the baseline survey, you will be assigned at random, with 50% chance, into one of two groups: 1) Woebot for Substance Use Disorders or 2) Wait-list control group.

Group 1: Woebot for Substance Use Disorders Program

After the baseline survey, you will participate in a 8-week program that will include daily lessons delivered through the Woebot mobile application. Each interactive lesson will take approximately 10 minutes to complete and you will be asked to give a "thumbs up" or a "thumbs down" after completing each lesson. Also, you will be asked to complete a total of three questionnaires: one at the beginning of the 8-week program, one at the 4-week mark, and one at the end of the 8-week program. You have the right to refuse to answer particular questions.

Group 2: Wait-list Control Group

The wait-list control group will receive access to the Woebot for Substance Use Disorders program after completing the final survey. You will be asked to



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complete a total of three questionnaires: one at the beginning, one at the 4-week mark, and one at the end of the 8 week mark. You have the right to refuse to answer particular questions.

This research hopes to: 1) compare the two groups to differences in substance use outcomes, and 2) assess and analyze the impact of COVID-19 in each group.

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.

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:

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



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- 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.

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.

Woebot is not designed for crisis service. However, when Woebot detects crisis language, it confirms with the user. If the user confirms, Woebot offers resources (9-1-1, suicide crisis hotlines).

Woebot is 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 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



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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.

POTENTIAL BENEFITS

You may benefit from participation by gaining awareness of your substance use and potentially reducing your substance use during COVID-19.

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 and ways to help people during a pandemic.

You may benefit from having access to a digital therapeutic 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.



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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.

CONFIDENTIALITY

Identifiers might be removed from identifiable private information and, after such removal, your information will not be used or distributed for future research studies even if all identifying information is removed.

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 Woebot's substance use disorder 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



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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 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 study?

The purpose of the study is to test different ways of helping people with substance use disorders. 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



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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, weight, height, drug use, IP address, and 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 Labs

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 \$25 Amazon gift card after completing each assessment. Total possible amount of payment per participant is \$75.

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 at Woebot, the company collaborating on this study.

Alison Darcy, PhD, is CEO & Founder of Woebot, the company collaborating on this study.

Sarah Pajarito is a research scientist at Woebot, the company collaborating on this study.

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 costs. If you are unable to pay for such costs, the Protocol Director will assist



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you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

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.

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;
- 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;



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- 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: _____

Please print a copy of this page for your records.

