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Study Title: Context-Aware Mobile Intervention for Social Recovery in Serious Mental Illness (mSITE)

ClinicalTrials.gov ID: NCT05660070

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University of California, San Diego
Consent to Act as a Research Subject

Context-Aware Mobile Intervention for Social Recovery in Serious Mental Illness
IRB # 800874

Introduction

Drs. Eric Granholm and Colin Depp and colleagues are conducting this research and asking for your consent to participate. This section provides a summary of important information. The rest of the form provides additional details.

- Research is voluntary - whether or not you join is your decision. You can discuss your decision with others (such as family, friends or your doctor).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- Your decision will not affect your health care or any other benefits you may be entitled to.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or mention concerns before, during or after the research.

The purpose of this research study to find out more about the effectiveness of a therapy called Context-Aware Mobile Intervention for Social Recovery in Serious Mental Illness (mSITE). mSITE integrates brief in-person skills training, remote telephone coaching, and use of a mobile application (an "app") to improve engagement in social activities and reduce isolation.

During your initial visit, you will participate in an interview and complete tests that assess your psychiatric history, functioning, symptoms, and attitudes. The research staff will ask you about your medical history, as well as your daily functioning. You will also take tests of memory, attention, reasoning, and related abilities.

Participation in this study may or may not benefit you directly. You will receive no-cost skills training. You may experience greater symptom relief and a better level of functioning than with standard medication treatment, alone. Even if you do not personally benefit, your participation may help clinicians achieve a better understanding of the effectiveness of the treatments in this study.

The most commonly expected risks of the study are: 1) Feeling tired, bored, or annoyed or 2) Feeling uncomfortable with some of the questions asked may be uncomfortable; for example, 'Have you been feeling depressed in the past week?' However, be assured that all questions are ones routinely asked in doctor's offices.

Additional, detailed information about this research is provided below. Please feel free to ask questions before signing this consent.

Why have you been asked to participate, how you were selected, and what is the approximate number of participants in the study?
You have been asked to participate in this study because you have a diagnosis of schizophrenia, schizoaffective, bipolar I disorder or major depression with history of psychosis. Approximately 100 participants will be consented in the project.

What will happen to you in this study and which procedures are standard of care and which are experimental?
In addition to the information at the beginning of this form, here are some additional details about will happen to you if you agree to be in this study:

1. Evaluation: To find out if you are eligible for the study, you will complete a interview and tests that assess your psychiatric history, symptoms, and attitudes. The research staff will ask you about your medical history, past and current medications, hospitalizations, as well as alcohol and drug use. You will be asked about your daily functioning and ways you cope with problems and think about your symptoms. You will also take tests of memory, attention, reasoning, and related abilities. Most of these will be done during the interview with study staff, but some will be paper and pencil tests or computerized tests and the movements of your eye will be recorded while you do some tests.

This evaluation, with the exception of the initial interview, will be repeated at 8, 12, 18, and 24 weeks after you enter the study.

You will also be asked to use a handheld mobile device, such as a smartphone, to record your experiences during the study. You will be trained to use the device and then you will be asked to answer questions each day throughout the study. Each questionnaire will take approximately 2 minutes to complete and will ask questions about your social and environmental contexts, activity and behavior, and your feelings.

2. Intervention: You will attend 8 weekly, individual skills training classes with a facilitator. During the sessions, you will set a meaningful recovery goal and identify steps to achieve the goal. You will learn important skills that will help you accomplish these steps through discussion, completing at-home practice, and responding to questions or suggestions on the mobile device. After completing the 8 in-person sessions, you will complete remote coaching for 15 minutes each week to address check-ins about device use and how skills learned during the in-person sessions are being used, and to discuss progress towards your goals.. Throughout the duration of the study, you will carry a mobile device. The device will prompt you respond to questions, practice skills, and work towards your recovery goal. The device will also log your location and if you are engaging in any interactions with other people so that the mobile device can personalize the prompts.

3. Recording: Participation in this study will involve recording portions of the assessment visit, such as the interview and the intervention sessions. The purpose of recording is for supervision of study staff and quality assurance. These recordings will only be reviewed by Drs. Granholm and Depp and their colleagues and will be used to ensure that the facilitators are following the intervention manual and that the research assistants are accurately administering the assessments.

Recording during the assessment visits is not required for participation in this study; however, it is important that study staff record the skills training and remote coaching sessions. You may refuse to be recorded or request that the recording be stopped at any time during the assessment visits. You may erase the recording up to a few minutes before the recording is stopped. These recordings will be kept in a locked cabinet in the Dr. Eric Granholm's lab, with only an identification number and not your name, and all recordings will be destroyed according to an approved protocol.

☐ I do give permission for study staff to record my research-related activities.
☐ I do not give permission for study staff to record my research-related activities.

4. <u>Mobile Data Collection</u>: An important component of the intervention is the use of specific information to determine which skills should be prompted, as well as when and where. For this to work properly, an app installed on the mobile device collects data about social interactions (i.e., how often the conversations occur and how long they last), nearby sounds, and social aspects of phone usage (e.g., how many and how long the phone calls last, and the number of text messages), but does not record the conversations. The app also collections location information, such as distance traveled and number of and duration in places visited, including home and other locations, as well as physical activity levels, sleep, and phone use (battery percentage, light intensity, phone access and use. You will also be asked to complete weekly diary responses. To protect your privacy, the app does not collect phone numbers, content of text messages, or record any conversations. Only summary information is uploaded when the phone is being charged and has WiFi or data services, and data on the phone are then erased and the phone can be remotely reset if lost. All of this information will be combined together over the period of data collection. The use of this data is an important component of this project. If you do not wish to consent to the use of this data, you should not enroll in the project.

5. <u>Future Research:</u> You will be asked if you are interested in getting information about future research studies. If you are interested, we will contact you with information about these studies and you can decide if you want to participate in them or not. These additional studies may or may not be separate from the present study, and your decisions about them will not affect your ability to continue participation in this study.

☐ I **am** interested in getting information about future research studies.
☐ I **am not** interested in getting information about future research studies.

You may withdraw your permission to be contacted at any time by contacting the study Project Manager, Dr. Jason Holden, at (858) 246-2517.

What risks are associated with this study?
In addition to the risks mentioned at the beginning of this form, participation in this study may involve a potential loss of confidentiality. Answers and responses during visits, which include medical and mental health information, will be written down. While this information will be de-identified and will be stored on password-protected computers or in locked filing cabinets that are themselves stored in locked facilities, it is theoretically possible that this information may become public in the event of theft or error. That said, this possibility is extremely unlikely. The

study investigators have conducted clinical research for over 20 years without ever experiencing such an event.

The evaluation procedures are long and require time and concentration. Some of the questions you will be asked will be personal and may cause you some discomfort, anxiety, sadness, and irritability, and you may become tired. The research assistant will minimize these discomforts by offering frequent rest periods when needed. You may also become anxious or uncomfortable during the intervention sessions. The facilitators will attempt to minimize your discomfort by discussing these feelings with you. You may decline to answer any questions or decline any procedures that make you feel uncomfortable. You may also become annoyed when the mobile device alerts you to answer questions or experience some discomfort from carrying the mobile device around in a pocket. Again, you may decline these procedures at any time, should you become uncomfortable.

Because this is a research study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?
The alternative is to not participate in the study.

What happens if you change your mind about participating?
If you decide that you no longer wish to continue in this study, you may notify any member of the study team at any time. You will be asked to come to the research office for about 15 minutes (optional) to complete questionnaires.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons: Drs. Granholm and Depp and colleagues determine that the potential benefits of the study do not outweigh the potential risks of the study.

You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
In consideration for your time and travel, you will be compensated $50 for completing the initial assessment visit and for the visits at Weeks 8, 12, 18, and 24. You will be paid at Week 8 (includes baseline and Week 8 assessments), Week 18 (includes Weeks 12 and 18), and Week 24. You can also earn up to $49 more for completing surveys on a mobile device following the initial visit and again at Weeks 8, 12, 18, and 24. You may receive up to $495 for participating in this research study. In addition, you will be provided refreshments and meals during assessment visits.

Are there any costs associated with participating in this study?

There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research participant or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. Research records may be reviewed by the UCSD Institutional Review Board.

During the research, if we learn you are having thoughts about suicide or hurting yourself or others, the research staff will ask you more questions about your thoughts. Based on your response, the staff may provide you with help to get treatment. This may include:

- working with you to contact your doctor,
- contact a trusted family member, or a therapist to discuss your thoughts,
- or work with you on a plan that may include getting you to a hospital for safety

Drs. Granholm and Depp and their associates are not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. If Drs. Granholm or Depp or their associates determine reporting to authorities, or other health agencies is necessary because of imminent serious danger to yourself or others, then they would only disclose information in your records, such as your current location and potential risks, to the extent necessary to prevent such imminent danger.

Your research records will be labeled with a code number. The list that matches your name with the code number will be kept in a locked file in the research team's office. Any research records that identify you will be kept only as paper records in locked storage or on password-protected computers.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate may not disclose or use information, documents, or biospecimens 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 unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research *unless* there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research participants.

The Certificate cannot be used to refuse a request for information from personnel of 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 the project or for information that must be

disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also 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 research to release it.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where de-identified study data from many NIH studies are stored and managed. Sharing your de-identified study data helps researchers learn new and important things about brain science more quickly than before.

De-identified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. The study researchers will have to collect your personal information from you in order to make that code number. The code number cannot be used to identify you. The study researchers will never send your personal information to NDA.

It is possible that you will participate in more than one study that sends data to NDA. NDA can connect your data from different studies by matching the code number on your deidentified data from each study. This data matching helps researchers who use NDA data to count you only one time. It also helps researchers who use NDA to better understand your health and behavior without knowing who you are.

During and after the study, the study researchers will send de-identified study data about your health and behavior to the NDA. Other researchers across the world can then request your de-identified study data for different research projects. Every researcher (and the institution to which they belong) who requests your de-identified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to NDA. You can still participate in this research study even if you decide that you do not want your data to be

added to NDA. If you know now that you do not want your data in NDA, please tell the study researcher before leaving the clinic today. If you decide any time after today that you do not want your data to be added to NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available on-line at http://nda.nih.gov.

Will you receive any results from participating in this study?
You will not receive any results from this study. The interview questions and tests used in this study are for research purposes and are not intended for diagnostic or clinical purposes.

Who can you call if you have questions?
This study has been explained to you and your questions have been answered. If you have other questions or research-related problems, you may contact Dr. Eric Granholm at 858-534-2542 or the study Project Manager, Dr. Jason Holden, at 858-246-2517.

You may call the Human Research Protections Program Office at 858-246-HRPP (858-246-4777) to inquire about your rights as a research participants or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____
Participant's signature Date

_____ _____
Signature of the person conducting the informed consent discussion Date