Enhancing Social Functioning in Schizophrenia Through Scalable Mobile Technology
NCT03404219
Unique Protocol ID: 1 R21 MH111501-01
Version date 8.7.2019

Protocol Title: Enhancing Social Connection through Mobile Technology
Principal Investigator: Daniel Fulford, PhD
Description of Subject Population: Persons with a diagnosis of schizophrenia or schizoaffective disorder
Version Date:

Introduction

Please read this form carefully. The purpose of this form is to provide you with important information about taking part in a research study. If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions.

Taking part in this research study is up to you. If you decide to take part in this research study we will ask you to sign this form. We will give you a copy of the signed form.

This study is being conducted at two sites: Boston University and San Francisco State University.

The person in charge of the Boston University site is Daniel Fulford, PhD. Dr. Fulford can be reached at (617) 358-2889, and by email at amplab@bu.edu. The person in charge of the San Francisco State University site is David Gard, PhD. Dr. Gard can be reached at (415) 405-2473, and by email at dgard@sfsu.edu. We will refer to these people as the "Principal Investigators" throughout this form.

Why is this study being done?

The purpose of this study is to examine the use of a mobile phone application designed to help improve social connection in people with schizophrenia and schizoaffective disorder. People with schizophrenia and schizoaffective disorder often report a desire to socialize but sometimes lack motivation to do so. This application is designed to provide tools to help increase social connection.

Other methods that target these impairments usually take place at mental health clinics, but there is a growing recognition that people with schizophrenia and schizoaffective disorder could benefit from assistance outside of a clinical setting.

Study Title: Motivation and Skills Support (MASS)
IRB Protocol Number: 4921
Consent Form Valid Date: 08/07/19
Study Expiration Date: 08/06/20

We are asking you to take part in this study because you have indicated that you might benefit from such a mobile phone application. About 30 participants will take part in this research study.

How long will I take part in this research study?

We expect that you will be in this research study for approximately 60 days. During this time, we will ask you to test a mobile phone application over a 60-day period. Before the 60-day period, we will have you come into our laboratory for approximately 4 hours and set you up with the phone and application as well as complete diagnostic and clinical evaluations. You will then test the application for 60 days. You will be asked to return after the 60-day intervention period for a termination session to complete outcome measures. This visit will last approximately 2 hours. Finally, you will be asked to return one final time after 90 days for a follow-up assessment which will also last approximately 2 hours.

What will happen if I take part in this research study?

If you agree to take part in this study, we will ask you to sign the consent form before we do any study procedures. The mobile phone portion of the study will be completed during your daily activities outside or at home. The in-person portions (before and after) will take place at either Boston University or San Francisco State University.

During your first study visit you will be provided with consent, clinically evaluated for a baseline assessment, and introduced to the mobile application. You will be asked questions about your social functioning, mood, and psychiatric symptoms. Your social cognition and general cognition will also be assessed.

After the interview and assessment part of the visit, you will be introduced to the self-monitoring component of the application. Following this visit, the 60-day trial period will begin. During this period, you will receive notifications on the phone 2 times per day, 7 days per week. We will be tracking your use of the application, including your location using GPS and your movement using the phone's accelerometer. We will also monitor use of the application and call you to address any issues you may encounter. We will check in with you periodically to discuss the mobile application. At the first visit we will explain all three components of the application: the modeling videos, the social motivation feedback, and the goal support. At the conclusion of the 60-day period we will ask you to return for a meeting in which you will be evaluated once more. Finally, you will be asked to return after a 90-day period for one last evaluation.

Audio and Video recording

In order to ensure we collect accurate information, we would like to audio and video record you during the three interviews we conduct for this study. If you are recorded it will be possible to identify you in the audio and video. We will store these recordings in a password protected

computer and only approved study staff will be able to see the recordings. We will label these recordings with a code instead of your name. The key to the code connects your name to your recording. The researcher will keep the key to the code in a password-protected computer. Recordings will be stored for 7 years, or fewer if you request that they be deleted.

Do you agree to let us audio/video record you during this study?

_____YES _____NO _____INITIALS

How Will You Keep My Study Records Confidential?

We will keep the records of this study confidential. We will assign you a unique study ID code for the research information that we collect and no identifying information will be included with the data. Only the Principal Investigators and members of the research team will have access to the link between your data and your identifiable information. We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records.

We will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

If, during your participation in this study, we have reasonable cause to believe that child/elder abuse is occurring, he must report this to authorities as required by law. The researcher will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

If, during your participation of this study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself or others, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not able to assure confidentiality.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of his research team
- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- The sponsor or funding agency for this study: National Institute of Mental Health
- Federal and state agencies that oversee or review research

All data collected for this study will be kept confidential. Hard copy data will be stored in paper form, in binders, in locked cabinets in the Principal Investigator's locked office. All electronic data will be password protected and stored on a secure network server. Only the Principal Investigators and members of the research team have access to the data. The results of this research study may be published or used for teaching. We will not put identifiable information on data that are used for these purposes.

Ethica, the maker of the mobile phone app, provides assurances of privacy (can stop data collection, and delete collected data) and security (data is encrypted), but we cannot guarantee the security of the mobile phone app.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. 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

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 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, for example, if there is a court subpoena, 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 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 the project that is needed for auditing or program evaluation by the National Institute of Mental Health (NIMH) 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 does not prevent the researchers from voluntarily disclosing, without your consent information that would identify you as a subject in this research study if we: 1) are concerned that you may be suicidal (thinking about killing yourself) or at immediate risk of seriously harming yourself or others, or 2) learn about serious harm to your or someone else such

as child abuse or elder abuse. Under these circumstances we will notify the appropriate people (such as your personal doctor, counselor, Department of Social Services, or other authorities).

Study Participation and Early Withdrawal

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. The standard medical care for your condition will remain available to you. If you decide to withdraw from this study, the information that you have already provided will be kept confidential. You will also have the option of turning off the app at any time – we will show you how to do this and provide written instructions for you to take with you today.
If the phone is lost, that we will do whatever we can to replace the phone. If the phone cannot be replaced (e.g., due to budget availability), you may be notified that your participation in the study will be discontinued

Future Contact

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University or San Francisco State University.

Do you agree to let us contact you in the future?

_____YES _____NO _____INITIALS

What are the risks of taking part in this research study?

You may feel some frustration when practicing some of the behavioral exercises the application suggests to you. You may take a break from the application or reach out to research staff if this is the case. You always have the option of refusing to answer any question on any questionnaire, or in any interview, whether in person or by phone and you have the option of not completing any portion of the study. In such a case you can leave the question blank on a questionnaire or you can just let the researcher know that you do not want to answer the question.

Loss of Confidentiality

The main risk of allowing us to use and store your information for research is a potential loss of confidentiality. We will protect your confidentiality by labeling your information with a code and keeping the key to the code in a password-protected computer. All hard copy data will be stored in paper form, in binders, in locked cabinets, in a locked office in the Principal Investigators' offices. Electronic data will be stored on encrypted computers only accessible to study staff by password and the appropriate digital credentials.

There is also the possibility that remote tracking using GPS and accelerometer may make you feel uncomfortable, or make your symptoms worse. As outlined above, you will be able to turn off the app at any time should it make you feel uncomfortable.

Are there any benefits from being in this research study?

There are no known direct benefits for taking part in this study. Findings from this study will speak to the promise of mobile phone-based tools to support social connection in people with schizophrenia or schizoaffective disorder.

What alternatives are available?

The alternative is to not participate in this study.

Will I get paid for taking part in this research study?

After passing an initial screen, you will receive $15 per hour for completing the initial baseline evaluation. The total baseline evaluation will take approximately 4 hours. If you complete the 60-day mobile application testing period you will be paid an additional $50. You will also receive $15 per hour for completing the 2 follow-up assessments (approximately 2 hours per visit). We will also give you the mobile phone used during the study to keep. If you do not complete the entire study, we will pay you for the parts you do complete. If you complete a diagnostic interview as a part of an initial screen, you will be paid $10 for completion of that interview (the $15 per hour rate begins after completing that interview).

What will it cost me to take part in this research study?

There are no costs to you for taking part in this research study.

What happens if I am injured as a result of participating in this research study?

If you are injured as a result of taking part in this research study, we will assist you in getting medical treatment. However, your insurance company will be responsible for the cost. Boston University and San Francisco State University do not provide any other form of compensation for injury.

If I have any questions or concerns about this research study, who can I talk to?

Boston University Contact: Daniel Fulford, PhD (Investigator)
Phone: 617-358-2889
Email: amplab@bu.edu

San Francisco State University Contact: David Gard, PhD (Investigator)
Phone: 415-405-2473
Email: dgard@sfsu.edu

If you have questions about your rights as a research subject or want to speak with someone independent of the research team, you may contact the Boston University IRB directly at 617-358-6115.

Statement of Consent

I have read the information in this consent form including risks and possible benefits. I have been given the chance to ask questions. My questions have been answered to my satisfaction, and I agree to participate in the study.

SIGNATURE

_____
Name of Subject

_____ _____
Signature of Subject Date

I have explained the research to the subject and answered all his/her questions. I will give a copy of the signed consent form to the subject.

_____
Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

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