Understanding Social Situations (USS): Training to Improve Social Function in People With Psychosis

NCT04557124

February 13, 2023

WHAT WILL HAPPEN IF YOU TAKE PART IN THE STUDY?

Beginning of study assessments

Screening assessment:

If you decide to participate in this study, after you sign this consent form, clinically trained staff will obtain your background information (like age, education etc.). They will also ask you about your medical history and psychiatric symptoms, in order to confirm your psychiatric diagnosis, and may review your medical record. You will also be asked to do some tasks measuring attention, memory, ability to solve problems, and other thinking skills. The screening procedures are expected to last less than 2 hours.

Additional testing at beginning of study:

If, based on the results of the screening, you meet all criteria for study participation, you will be asked about any current psychiatric symptoms you may be experiencing, along with some general questions about your day-to-day life and how you spend your time. You will also be asked to fill out some questionnaires, along with additional thinking skills tasks. All together, this additional testing at the beginning of the study is expected to take about 60-90 minutes.

The screening assessments and additional testing can be done over several sessions, at your convenience.

Training sessions

After the testing, you will be randomly assigned (like the flip of a coin) to one of two different types of training courses. You will have an equal chance of being assigned to either of the two trainings. One training focuses on how to make good judgments about what other people may be thinking or feeling in social situations, and why people might act in certain ways in different situations. The other training focuses on different strategies for handling everyday problems and stressors. Both trainings are done in one-on-one sessions with a research staff member. There will be 16-20 training sessions, each about 45-60 minutes long. We will ask you to attend 2 training sessions per week, so the total training time should be about 2 months.

Recording picture or voice:

We would like to video-record the training sessions to make sure that they are being done correctly. The videotapes will only be accessible to research staff and will not leave the protected VACHS environment. By initialing below, you provide your consent to allow the training sessions to be video-recorded.

I agree to have my training sessions video-recorded _____

Participant's Initials

Mid-training assessments

After you are about half way through with the training sessions, or about 1 month in, you will be asked to repeat a couple of the assessments you did at the beginning of the study including a questionnaire about how you have been spending your time. This assessment should take about 15 minutes.

Post-training assessments

After you've completed the training sessions, or about 2 months in, you will be asked to repeat some of the interviews and tasks you did at the beginning of the study. You will again be interviewed about your current psychiatric symptoms and how and with whom you spend your time, you will again be given paper and pencil tasks measuring concentration, memory and ability to solve problems, and you will again be given several other tasks including questionnaires about how you spend your time. These tasks and interviews will take about 2 hours, and you'll be given the choice of whether to do them in a single session or over several sessions.

Follow-up assessments

Two months after you've completed the training sessions, or about 4 months into the study, we will again give you the same measures you did during the post-training assessment. These tasks and interviews will again take about 2 hours, and you'll be given the choice of whether to do them in a single session or over several sessions.

Smartphone surveys

At the time of the testing at the beginning of the study, the post-training testing, and the follow-up testing, you will also be asked to complete some brief "real-time" surveys about how you spend your time and how you are feeling. At each of the three timepoints, a link to these surveys will be sent to your smartphone 4 times a day for a period of 7 days. Each set of questions should take about 3 minutes to complete, and the surveys will be available for completion for one hour. You should not answer survey questions if you are driving. If you receive the link to the survey questions while you are driving, you should wait to fill out the survey until you are done driving or pull over to the side of the road before beginning the survey. A study phone will be provided for you to use for the duration of the study, and at the end of the study you will be provided with details about how you can keep the phone and transfer service into your name, if you wish to do so.

Pandemic Procedures

In order to preserve your safety and the safety of study staff during the novel coronavirus pandemic, we will be conducting the majority of study assessments and other procedures remotely using telehealth visits for all participants recruited during the COVID-19 pandemic. In order to accomplish this:

- The majority of study procedures (assessments and training sessions) will take place by VA-approved telehealth, which may be video or phone call.
- For any in-person visits that take place, we will contact you one day prior the appointment and ask about any symptoms of viral infection or exposures; you will be asked to use hand sanitizer upon entering the office.
- You will be required to follow up-to-date VACHS instrutions for use of personal protective equipment (PPE) while conducting study procedures in person. This may include but not be limited to wearking 2-ply facemasks and face-shields. We will provide the necessary PPE for you.
- To enhance your safety, staff will utilize masks, gloves, faceshields and social distancing during study visits, and will sanitize the office between each in-person visit and at the end of the day.

WHAT IS EXPECTED OF YOU IF YOU TAKE PART IN THIS STUDY?

- Keep your study appointments. If you cannot make a scheduled appointment or miss one, please contact research staff to reschedule as soon as possible.
- Attend the beginning of study, mid-training, post-training and follow-up assessments as scheduled.
- Attend the training sessions.
- Participate in the “real-time” smartphone surveys 4 times a day for 7 days, at 3 different time points during the study.
- While participating in this research study, do not take part in any other research project without first discussing with the research team. Taking part in other research studies may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT YOU HAVE IF YOU TAKE PART IN THIS STUDY?

Some people may experience discomfort during the interviews when they are asked to talk about psychiatric symptoms or their psychiatric history. You have the right to refuse to answer any questions. You may choose to stop doing any of the tasks at any time, and need only answer those questions or participate in those procedures with which you feel comfortable. You may also become tired or frustrated during the training or some of the assessments. You can take breaks at any time, and you will be given the opportunity to break up the testing into multiple sessions, if you prefer.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, your participation may lead to knowledge that may help others. You will be helping us to evaluate a new treatment to improve the day-to-day interactions and quality of life of people diagnosed with psychiatric disorders.

HOW WILL YOUR PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

- Paper documents are locked in filing cabinets in locked offices.
- Information collected electronically will be done so on computers protected with passwords and stored on the secure VA network.
- Only authorized persons will have access to the information gathered in this study.
- Only a code number will identify your research records. The code number will not be based on any information that can identify you (for example, social security number, initials, birthdate, etc.)
- The master list linking names to code numbers will be kept separately from the research data.

There are times when we might have to show your records to other people. For example, our local Research and Development Committee, VA officials, and other study monitors who may look at or copy portions of research records that identify you.

Clinical information may be shared with your clinician when it is in the interest of good clinical care as determined by the principal investigator, Dr. Joanna Fiszdon. Also, any information that is gathered during research procedures that could be helpful in your rehabilitation may be shared with the clinicians involved in your care. This may include test results along with survey and interview responses.

As part of the assessments, we will ask you questions about psychiatric symptoms. If, in the course of our study procedures, we have reason to be concerned for your safety or feel that you may be a threat to the safety of others, we will inform your VA clinician who may wish that you be evaluated in the Psychiatric Emergency Room at VA Connecticut Healthcare System. Your clinician or the psychiatrist on duty might decide to hospitalize you, even if you do not wish to be hospitalized. If we are unable to contact your clinician and have concerns about your safety, we may escort you to the psychiatric emergency room, where you will be evaluated, and a decision may be made to hospitalize you. If we become concerned about your welfare during a telehealth visit, we may contact 911 and request a welfare check.

The smartphone assessments are conducted using Qualtrics and your phone number will be stored there for the duration of the study. A study smartphone will be provided to you for this purpose. Data analysis will also be done at Yale, although the data we share with them will not contain any identifiable information about you.

RE-CONTACT

We would like your permission to be able to contact you in the future, to either follow-up on the current study or with an invitation to participate in another study. If you agree to be contacted in the future, please initial below.

I agree to be contacted for future research studies_____
Participant's Initials

Storage and Future Use of Data:
Your research data will be stored by the study Principal Investigator, Dr. Joanna Fiszdon, at VACHS indefinitely, with access restricted to authorized research personnel. Identifiers might be removed from the identifiable private information that is collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

Medical Record
We will include information about your study participation in your medical record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records apply to your VA record.

Clinical Trial
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.

WHAT ARE THE COSTS TO YOU IF YOU TAKE PART IN THIS STUDY?
You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

IS THERE PAYMENT TO YOU IF YOU TAKE PART IN THIS STUDY?

You will be paid $25 for the screening assessment at the beginning of the study, and, if you are eligible to continue, $25 for additional testing at the beginning of the study, for a total of $50. You will be paid $10 for each training session (between 16-20 sessions). You will be paid $10 for participating in the midpoint assessment (around 1 month into the study). You will be paid $50 for participating in the post-training assessments (around 2 months into the study). You will be paid an additional $50 for participating in the follow-up assessments (around 4 months into the study). You will also be paid $1 for each "real-time" survey assessment ($4/day), which are administered 4 times a day for 7 days at the beginning of the study, at post-training assessment, and at follow-up assessment. Maximum total payment for study participation is up to $444.

You will also be provided with a smartphone to use for the duration of the study and will be allowed to keep this phone. Details will be provided to you at the end of the study about how

you can transfer service into your name.If you complete at least 80% of your "real-time" survey assessments, you will be entered into a raffle to win an additional $100 prize.

In addition to the above study payments, if you refer a friend who may be eligible for this study you will be paid $10. In order to qualify for the payment, the person you refer must pass the preliminary phone screening and agree to come in for an in-person meeting to learn more about the research study.

Additional reimbursement for travel to/from the research study may be available depending on individual situations as determined by the Principal Investigator. All payments will be by electronic fund transfer (ETF) or by check issued by VA through Austin Financial Services Center. Your social security number will be used on the documents to set up these payments. These study payments are subject to withholding for outstanding federal debts, such as defaulted student loans, interstate child support, back taxes, etc. These payments will also generate Internal Revenue Service Form 1099 regardless of amount. An alternative payment option is via a gift certificate to be used at the VA Canteen store or cafeteria.

WHAT WILL HAPPEN IF YOU ARE INJURED BECAUSE OF YOUR BEING IN THE STUDY?
If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study subject with study procedures. Emergency and ongoing medical treatment will be provided as needed.

There are no plans to provide compensation for disability or other losses occurring over the long term or if an injury becomes apparent after your participation in the study has ended. However, by agreeing to participate in this research study, you are not waiving or giving up any legal rights to seek compensation. If you have any questions about your rights as a subject, you may contact the Chairman of the Human Studies Subcommittee at (redacted). If you have any complaints, concerns or pertinent questions regarding the conduct of this study, or if you have any questions about compensation for injury, you may contact the Human Studies Coordinator in the Research Office at (redacted).

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:
The VA Connecticut Research Coordinator at (redacted), OR
Dr. Joanna Fiszdon at (redacted) and

AFTER HOURS:
Psychiatric Emergency Room at (redacted).

WHO ELSE MAY YOU CONTACT IF YOU HAVE QUESTIONS?

If you have questions about your rights as a study subject, or you want to make sure this is a valid VA study, you may contact the Chairman of the Human Studies Subcommittee at (redacted)

If you have questions, complaints or concerns about the study or if you would like to obtain information or offer input you may call Dr. Joanna Fiszdon at (redacted).

DO YOU HAVE TO TAKE PART IN THE STUDY?

Participation is voluntary and refusal to take part in this study, or withdrawing from the study, will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part in this study at any time without any penalty or loss of benefits. If you withdraw from the study you can still receive the same standard of care that you otherwise would have received. Data already collected prior to your withdrawal will still be used but no further information will be collected. If you decide to withdraw from the study, the data plan provided to you for your smartphone will be deactivated. We will ask you to return the phone to the research staff. If you choose not to return the phone, it will be locked and unable to be used to start new wireless service

RIGHT OF INVESTIGATOR TO TERMINATE YOUR PARTICIPATION

Your participation in this study may be terminated or suspended if you are hospitalized, or if your clinician feels that your participation in this study is interfering with your care or is making your symptoms worse. If, in the opinion of the principal investigator, a participant is no longer appropriate for the study, his or her participation may be discontinued without regard to the participant's wishes.

WILL YOU BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If any new findings are developed during the course of the research which may affect your willingness to continue in the research, you will be contacted and provided with the information.

Subject Name: _____ Date:_____

Title of Study: Understanding Social Situations (USS):Training to improve social function in people with psychosis

Principal Investigator: Joanna Fiszdon, Ph.D. Version Date: 02/13/2023

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A member of the research team has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study You also confirm that you have read this consent document, or it has been read to you. You will receive a copy of this consent document after you sign it.

I agree to participate in this research study as it has been explained in this document.		
_____ Subject's Name	_____ Subject's Signature	_____ Date

_____ Person Obtaining Consent	_____ Person Obtaining: Signature	_____ Date