Consent to Participate in Research

Title of Research Study: Virtual Reality Job Interview Training: An Enhancement to Supported Employment for Individuals with Severe Mental Illness; IRB# 202936

Investigator: Dr. Neil Jordan, Ph.D.

Supported By: This research is supported by National Institute of Mental Health.

Key Information about this research study:

The following is a short summary of this study to help you decide whether to be a part of this study. Information that is more detailed is listed later on in this form.

The purpose of this study is to test if a virtual reality job interview training tool helps improve job interview skills and helps get a job for individuals receiving Thresholds employment services. You will be asked to attend a focus group for approximately 60 minutes so we can ask about your experinces using the virtual reality job interview training.

The primary risk of participation is boredom from completing role-plays and surveys. The main benefit is that you may have increased chances of getting a job.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you recently trained with Virtual Reality Job Interview Training at Thresholds and we would like to ask your opinions about the use of the training and how Thresholds' provided you with access to using the training.

How many people will be in this study?

We expect to have 3-5 feedback groups with 6-8 participants in each feedback group.

What should I know about participating in a research study?

- Someone will explain the research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

What happens if I say, "Yes, I want to be in this research"?

As a participant in this study, we will schedule a group meeting for members who trained with Virtual Reality Job Interview Training at Thresholds Inc. (2240 W. Ogden Ave,, Chicago, IL 60612). The feedback group will take approximately 60 minutes. There will be 1-2 research assistants present who will help guide the group discussion. These questions will ask about your views on the approach used by Thresholds to deliver the virtual reality training to you, advantages of using the virtual reality training compared to typical services, and available resources that might help or hurt the use of virtual reality training at Thesholds. In addition, we will video record the focus group to make sure that we do not miss or forget any feedback from participants. This video will be destroyed as soon as we convert all of the video into text. To participate in the focus group, it is a requirement to be video-recorded.

your chance of parole or release.

Is there any way being in this study could be bad for me?

There are no known risks for this study as you will simply be asked to share your opions about the process of using the training in a group setting.

What happens if I do not want to be in this research?

Participation in research is voluntary. You can decide to participate or not to participate.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time and it will not be held against you. At any time in the study, you may decide to withdraw from the study. If you withdraw no more information will be collected from you and we will not contact you further. When you indicate you wish to withdraw the investigator will ask if the information or materials already collected from you can be used in the research analyses. If you do not want your study data to be used then you need to provide a formal, written request to the research team.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution as well as representatives of the National Institute of Mental Health and other University research centers and University contractors who are also working on the study. We cannot promise complete confidentiality because other participants will be involved in the discussion.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). This Certificate says that the researchers on this study cannot share or use information that may identify you in the event of a legal action or court proceeding. For example, if there is a court subpoena asking for your information from this study, the researcher cannot give your information to the court unless you consent to it. Your information is protected by this Certificate and cannot be shared with 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); if you, yourself, have consented and agreed to share the information, including for your medical treatment; or if it is used for other scientific research (only when it is allowed by federal regulations protecting research subjects).

The Certificate cannot be used to refuse a request for information that is needed for auditing or program evaluation by NIH or for information that must be shared in order to meet the requirements of the Federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not stop you from voluntarily releasing information about yourself or your involvement in this research. If you want to share research information with 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.

A description of this clinical trial (NCT03049813) will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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 Institue of Mental 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.

Alcohol and Substance Abuse Information:
Federal Confidentiality Rules, 42 CFR Part 2, prohibit making any further disclosure of Alcohol and Substace Abuse information unless further disclosure of this information is expressly permitted by your written consent.

Mental Health Information:

This consent expires on December 31, 2025. _____. After this date, Northwestern University may not gather new information about you, use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless Northwestern University obtains permission to do so from you. Illinois State Law permits use and disclosure of your mental health information only to the extent specified in this document.

Illinois law does not allow the re-release of mental health and developmental disabilities information by the receivers of the information except in precise situations allowed by law.

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy.

The following entities may receive your health information:

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Unless you revoke your consent, it will expire on December 31, 2025.

Data Sharing: De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

We will not ask you about child [or elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

What else do I need to know?

If you agree to take part in this research study, we will pay you $15.

The focus groups will be video recorded for the purposes of transcribing the session and then the recordings will be deleted.

A description of this clinical trial (NCT03049813) will be available at http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can I talk to?

If you have questions, concerns, or complaints, you can talk to the person in charge of this study, Dr. Neil Jordan, at (312) 503-6137 or neil-jordan@northwestern.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Signature for Adult 18 or older

Your signature documents your permission to take part in this research.

_____ _____
Signature of participant Date

_____
Printed name of participant

_____ _____
Signature of person obtaining consent Date

_____
Printed name of person obtaining consent