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: 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 complete two job interview role-plays, learning and memory tests, and surveys about job interviewing. Some participants will then use the interview program and some participants will be on a waitlist to use the interview program. Participants will complete two more job interview role-plays and surveys after completing their use of the interview program. We expect that you will be in this research study for a total of 6 months after you complete the job interview training (or the waitlist) so that we can see if you obtained a job during that time.

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 be in in this study because you may have been diagnosed with a long-term mental health problem (like depression, bipolar disorder, or schizophrenia), you are a member of Thresholds, and you are looking for a job. This form has important information about why we are doing the study, what you will do if you choose to be in this study, and the way we would like to use information about you and your health.

How many people will be studied?

We expect about 200 people here will be in this research study.

What should I know about participating in a research study?

- Someone will explain this 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"?

First, to ensure that you are eligible for the study, research staff will look into your medical charts to confirm your past/current mental health diagnosis. Then, as a participant in this study, you will attend your first two study visits (each lasting approximately 2-2.5 hours) at a Thresholds location (see appendix A on page 7 for a full list of locations).

If you are selected for the computer-training program, we will also need you to come to the Individual Placement and Support program offices at Thresholds Inc. (2240 W. Ogden Ave, Chicago, IL 60612) or at your local Thresholds location (see appendix A on page 7) for 6 additional visits (lasting approximately 2 hours each, with 1 visit lasting 1 hour). We may also need you to come to the Clinical Research Program at Northwestern University Department of Psychiatry and Behavioral Science for three visits (each lasting approximately 2-2.5 hours). The Northwestern University offices are located at 680 Lake Shore Dr. Suite 1520; Chicago, IL 60611. We will inform you of the location and provide you with directions.

All participants will complete some research tests and the procedures are being done only for the purposes of this study. Also, if you are randomly assigned to the intervention group, you will use a computer program that may improve your job interviewing skills. All procedures are listed below:

Study Visit 1 at Thresholds (around 2.5 hours). During this visit you will complete the informed consent (around 20 minutes) that requires that you provide contact information for a collateral contact (e.g., family member, social worker), an interview that discusses your personal and mental health history (including drug use) (around 1 hour) and a short reading test (around 10 minutes). After these tests, we will determine if you are able to enroll in the study. For people who do not meet criteria, their participation ends at this time. Participants who are eligible to complete the study will complete self-reports on motivation, job interview confidence and anxiety, and comfort with technology (around 20 minutes). They will then will be scheduled for Study Visit2/3.

Study Visit 2/3 at Thresholds or Northwestern University (around 3.5 hours): During this visit you will complete additional tests that include: learning and memory tests (around 45 minutes), mental health symptoms assessment (around 30 minutes), work history interview (around 20 minutes), two assessments of your everyday living experiences (around 20 minutes), and lastly, two job interview role-plays (around 90 minutes) and a social performance test (around 10 minutes) that will be video-recorded. You can take breaks when you feel tired.

At the end of Study Visit 2/3, we will inform you if you will be placed into the computer-training group or the employment services as usual group. Your group placement is determined by a random process which places 60% of people into the computer-training group and 40% of people into the employment services as usual group. Participants in the computer-training group will return to Thresholds for 6 additional visits (Visits 4, 5, 6, 7, 8, and 9) (see below). The employment services as usual group will not participate in study visits 4 through 9.

Participants in this group can use the computer-training software after they have completed the 9-month follow up phone call.

Study Visit 4, 5, 6, 7, 8, and 9 (around 2 hours each) will consist of computer-training sessions. During Visit 4, research staff will teach you how to use the computer program. Briefly, the computer program requires you to take part in a pretend role-play where you will be interviewed by a virtual person on the computer screen. You will be given $10 at each session to cover the cost of your travel. After completing at least 10 virtual interviews you may require assistance to use the virtual interview tool at home with your own internet and computer. If you request to use the virtual interview tool at home then research staff will teach you how to do this during one of your computer-training sessions. Once you are at home, please call Thresholds project staff at 1-773-432-6301 or 1-773-572-5138 during regular business hours and they will walk you through using the virtual interview tool at home.

Study Visit 10 at Thresholds or Northwestern University (around 2 hours) will require participants from both groups to complete mental health symptoms assessments (around 45 minutes), self-reports on your motivation, job interview confidence anxiety, and health (around 25 minutes), a brief survey about your experiences using the virtual reality training (to be completed by the training group only), and lastly, two job interview role-plays (around 90 minutes) and a social performance test (around 10 minutes) that will be video- recorded. You can take breaks when you feel tired.

Monthly Check-in Telephone Calls (less than 10 minutes each) will require participants from both groups to complete a brief interview about your employment history in the past month. There will be 5 calls, each scheduled one month apart.

Study Visit 11 at Thresholds or Northwestern University (around 1.5 hours) will require participants from both groups to return 6 months after visit 10 to complete mental health symptoms assessments (around 45 minutes), self-reports on your motivation, job interview confidence and anxiety, and comfort with technology (around 20 minutes), two assessments about your everyday living experiences (around 10 minutes each), tests and questions about your living skills (around 20 minutes), and lastly, a brief interview about your employment history since visit 10.You can take breaks when you feel tired. If you have obtained a job by this time, your participation in the study will be complete after this visit.

Monthly Check-in Telephone Calls (less than 10 minutes each) will require participants from both groups to complete a brief interview about your employment history in the past month. There will be 2 calls, each scheduled one month apart. If you have obtained a job during this time, we will ask you ask you a few additional brief questions about your employment, and your participation in the study will be complete.

Follow-up Telephone Call (around 10 minutes) will occur about 9 months after visit 10 and will require participants from both groups to complete a brief interview about your employment history since visit 11.

The role-plays will be video recorded and studied by researchers. Video-recording of the interviews is required for participation. If you do not wish to be video-recorded, it will not be possible for you to take part in this study. The videos will only be observed by researchers to evaluate how well you performed during the role-play interviews. The video files will be password-protected and saved with the highest security measures available to Northwestern University.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include improving your job interview skills. Taking part in this study may also help us learn how to improve the process of organizing and providing this computer-training to individuals in the future.

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

There are rare psychological risks to participating in the study as you feel emotionally uncomfortable while answering questions about your mental health history. There are rare physical risks where you may feel tired when completing the study tests or you may feel nervous during the role-plays. If this happens, please tell the research staff so that you can take a break at any time.

There is a rare privacy risk that the Northwestern University computer server system where the videos are stored could be breached. We will reduce this risk by storing the videos on the server protected by passwords and a firewall.

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

You can leave the research at any time and it will not be held against you.

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. 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.

There are exceptions to the confidentiality of what you share with the research team. To protect you and others, confidentiality may be breached:

1. If you indicate your psychiatric symptoms have significantly worsened.
2. If you indicate that you plan to hurt yourself.
3. If you indicate that you plan to hurt someone else.
4. If you provide information indicating abuse or neglect of vulnerable individuals such as a child or the elderly.

If you share with us that you plan to hurt yourself or that your mental health symptoms have significantly worsened, our research team will inform Thresholds clinical staff and will try to work with you to get appropriate services to ensure your safety. If you share with us plans to hurt someone else, or 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.

In this study, you will be asked about illegal activities such as drug use. We will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, courts have subpoenaed (required release) research records. However, 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 (include NCT#) 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.

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 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 what will be reported, such as child abuse and neglect, or harm to self or others.

HIPAA Authorization:

In order to participate in this study, we need to obtain your health information from your past, present, and future medical providers. Your signature on this consent with HIPAA Authoriation is the means for getting access to that information. We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include

your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in your Thresholds agency services record
- Demographic information, including your name, telephone number, date of birth, race/ethnicity, and gender
- Medical history, including physical health diagnoses
- The types of employment and mental health services you have received
- Your employment history and activities
- Certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Substance abuse information: past or current diagnoses or reported use
- Mental Health information: past or current diagnoses

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.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the National Institute of Mental Health.

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 [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University and Thresholds, Inc. workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.

- Clinical affiliates, including but not limited the Rehabilitation Institute of Chicago (RIC), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

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

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Neil Jordan, Ph.D.

Institution: Northwestern University Feinberg School of Medicine Department: Psychiatry and Behavioral Sciences

Address: Abbott Hall, 12th Floor, 710 N. Lake Shore Drive, Chicago, IL 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

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.

Can I be removed from the research without giving my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include arriving to a research session visibly intoxicated. If a participant arrives at a research visit and appears to be psychiatrically unstable then he/she will be evaluated by a licensed clinician on the study team and appropriately referred to the

emergency room or primary mental health care provider. In these cases, the participant may be withdrawn from the study without their approval.

Compensation: If you agree to take part in this research study, we will pay you per completed visit where research assessments are collected. If a visit is not completed in full, you will be paid for the portions you completed. These payments are approximately $70 for Baseline Visit 1, $70 for Baseline Visit 2/3, $50 for Visit 10 and $40 for Visit 11. If you complete 3 out of 5 scheduled monthly check-in calls before visit 11 (5 calls in total), you will receive an additional $10. If you complete the two additional check-in calls before the 9-month follow-up telephone call, you will receive an additional bonus of $10 after the completion of the 9-month call. Participants will not be paid for Visits 4-9 when they use the intervention.

Thus, the total amount that can be received for the study is approximately $250 per participant for completing research assessments. Study participants will not be paid for completing research visits 4, 5, 6, 7, 8, and 9 because they are receiving a free intervention.

Most tests done in research studies are only for research and have no clear meaning for developmental, educational or health care. If the research with your identifiable information or biospecimens samples gives results that do have meaning for your health, the researchers will not contact you to let you know what they have found.

The video-recordings will only be used for research purposes, and will be kept by the Principal Investigator for a period of five years after the completion of the study and will then be discarded. The videos will be stored on a Northwestern University computer server, and protected by our highest security measures.

Documentation of Collateral Contact:

Participants will be excluded from the study unless they can provide a confirmed collateral contact with a friend or family member.

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

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.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team.

I agree	I disagree	
_____	_____	I am interested in attending the optional group feedback session conducted at Thresholds (around 1 hour) that will require participants from the computer-training group to sit with 5-7 other study participants from the computer-training group to discuss whether you thought the use of the computer-training was helpful and the process for providing to you was well-organized. Video-recording of the session is required for participation in the optional group feedback session.
_____	_____	I may be asked for permission to have a small part of an assessment audio-recorded.

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

My signature below documents that the information in the consent document and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____

Signature of witness to consent process Date

_____

Printed name of person witnessing consent process

Friend or Family Member

_____I agree to allow research personnel to contact my friend or family member if I cannot be reached by my phone or email, so that the study can contact me for visits or planned study telephone calls. I will provide the contact information on the next page.

Name: _____

Address: _____

City: State: Zip Code: Phone:

Appendix A: Thresholds Locations for Molly Delivery

12145 S. Western Ave., Blue Island IL 60406- "South Suburbs"

12151 S. Western Ave., Blue Island 60643- "New Freedom Center, South Suburbs" 4101 N. Ravenswood Ave., Chicago IL 60613- "4101"

4423 N. Ravenswood Ave., Chicago IL 60613- "Research Team Office" 5357 N. Broadway, Chicago IL 60640- "Peer Success"

734 W. 47th Street, Chicago IL 60609- “Bridge South”

4219 N. Lincoln Ave, Chicago IL 60618- “Young Adult Program” 3638 S. Kedzie Ave., Chicago IL 60632- “Bridge Southwest”

2240 W. Ogden Ave., Chicago IL 60612- “Supported Employment & Veterans Program” 5000 W. Roosevelt Rd., Chicago IL 60608- “Bridge West”

716 W. 47th Street, Chicago IL 60606- “Freedom Center, South”

2045 W. Grand Ave, Chicago IL 60612- “New Freedom Center, North” 120 S. LaSalle St., Chicago IL 60603- “HQ”

202 N. Schuyler Ave., Kankakee IL 60901- “Kankakee”

444 Frontage Rd., Northfield IL 60093- “New Foundations Center” 7400 Skokie Blvd., Skokie IL 60077- “North Suburbs”

777 Oak Lane, Westmont IL 60559- “Westmont”

109 S. Jefferson St., Woodstock IL 60098- “McHenry