

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in our research study, “Enhancing Community Mobility in Individuals with Serious Mental Illness Through Peer-Facilitated Travel Training: A Two-armed Waitlist Controlled Trial.” This first page provides a summary of this study and a full description of the study is available in later sections of this document.

What should I know about this research?

- This research will be explained to you in full.
- You can ask all the questions you want at any time.
- Whether you take part in this study is always up to you, you can choose not to take part, and you can agree to take part and later change your mind.
- Your decisions will not be held against you or affect the treatment or services you currently receive.

How long will I be in this research?

We expect that you will be enrolled in this research for 4 months.

Why is this research being done?

This research is being done to determine if peer-supported travel training increases community participation and mobility in people with serious mental illness.

What happens to me if I agree to take part in this research?

If you agree to be in this study, you will be randomly assigned to a bikeshare travel-training or a public transportation travel-training. The travel-training groups go through educational programs which will teach participants to use the given transportation method. All participants must participate in three hour-and-a-half long interviews- one at the beginning of the study, another at 2 months, and a final one at 4 months.

Could being in this research hurt me?

While there are no major risks associated with this study, there are inherent risks for everyone using public transportation, biking, and travelling in the community. In addition, interviews will contain questions some participants may find triggering or distressing. Finally, there is always the possibility for loss of confidentiality if someone else were to access your personal health information. Study staff will protect your personal information closely and have created safeguards to protect and properly store private information.

Will being in this research benefit me?

While being in this study may increase your ability to travel in your community, there are no guaranteed benefits of this research.

What other choices do I have besides taking part in this research?

The alternative to participating is not participating. You may choose not to participate or leave this study at any time.

DETAILED RESEARCH CONSENT FORM

Title of this research study: Enhancing Community Mobility in Individuals with Serious Mental Illness Through Peer-Facilitated Travel Training: A Two-armed Waitlist Controlled Trial

Investigators and Departments:

Gretchen Snethen, Ph.D., CTRS; *Temple University Department of Rehabilitation Sciences*
Beth Pfeiffer, Ph.D., OTR/L; *Temple University Department of Rehabilitation Sciences*

Why am I being invited to take part in this research?

We are inviting you to take part in this study because you have a schizophrenia-spectrum, major depression, or major affective disorder, you are between the ages of 18 – 65, you have the physical ability and the basic skills necessary to safely travel, and you told us that you are interested in using public transportation and riding a bicycle for transportation.

What should I know about this research?

- This research will be explained to you.
- You can ask all the questions you want at any time.
- Whether you take part in this study is always up to you, you can choose not to take part, and you can agree to take part and later change your mind.
- Your decisions will not be held against you in any way.
- Your decisions will not affect the treatment services you currently receive.

Who can I talk to about this research?

If you have questions, concerns, complaints, or think that being in this study has hurt you, you can contact the research team by phone at (215)204-3257, email at tucollab@temple.edu, or mail at:

The TU Collaborative
1700 North Broad St.
Suite 313
Philadelphia, PA 19121

This research has been reviewed and approved by an Institutional Review Board (IRB). IRBs are groups that protect the rights and well-being of human research participants. You can contact them at (215) 707-3390 or e-mail them at irb@temple.edu for any of the following reasons:

- You have questions, concerns, or complaints not being addressed 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 subject.
- You want to get information or provide input about this research.

You can also contact the Philadelphia Department of Public Health Research Participant Coordinator at (215) 685-0869 or email them at: research.participant.DPH@phila.org for any of the reasons mentioned above.

Why is this research being done?

People with psychiatric disabilities often say that without easy access to transportation they feel isolated and unable to be involved in their communities. Because of this we are looking at whether peer-supported trainings that teach travel skills will help people with mental health conditions feel more independent and have greater confidence in their travel skills and ability to participate in their community.

How long will I be in this research study?

We expect that you will be enrolled in this research study for 4 months. During that time, you will complete 3 interviews, answer short phone surveys once a day for 7 days after each interview, and participate in an intervention group which will have a time commitment of 2-3 hours a week for 8 weeks. We're aiming to enroll 180 participants total.

What happens if I agree to be in this research?

There are a few different parts of this study. All participants who are part of the study will do three different interviews with research staff. After consent, we will do one interview today, one in 2 months, and a final interview in 4 months. Interviews will be in-person or over a web-based video call (Zoom). In-person interviews can be done at your agency, at Temple, or at another quiet community location where you feel comfortable answering personal questions. Each interview will last about an hour and a half, and you will be asked questions about yourself, your mental health condition, your travel skills, and the places you go in the community. In addition, every day for seven days after each interview (21 times total) you will be asked to complete a travel log (The National Household Travel Survey), and then called by a research team member daily and asked to read the research staff your previous day's travel log. Each of these phone survey sessions should take 10-15 minutes.

After completing the first interview, you will be randomly assigned either to begin the intervention program immediately, or to be placed on a waitlist to then start the intervention program 8 weeks after initially consenting. After that, you will then be assigned to one of the travel intervention groups. You'll be assigned to one of the groups at random (bikeshare or public transit) and there is a 50% chance that you will be placed in either group. Neither you nor the research team gets to choose which group you are placed in, and you can't choose to switch into a different group. The intervention meetings and activities will be carried out by community integration specialists and peer support specialists, not the research staff you meet for the three interviews or talk to for the National Household Travel Survey. Below, the travel intervention groups are explained in greater detail.

Groups 1: Peer-facilitated travel training for bike share

If you are placed in this group, you will receive a 3-month membership to Indego, the bike sharing program of Philadelphia, and participate in an 8-week program which will support you to use the Indego bikes and successfully ride around the city independently. The intervention will include activities like attending educational sessions, identifying places you would like to go and planning how to get there, and participating in direct and individualized training with peer support specialists. The program schedule will include meeting 1 to 2 times per week.

Group 2: Peer-facilitated travel training for public transportation

If you are assigned to this group, you will receive a 3-month pass to SEPTA, Philadelphia's public transportation system, and participate in an 8-week program which will teach you the skills to be an independent and confident traveler on SEPTA. Participants will receive training on the basics of using public transportation, go on supervised trips, and do individual planning and identification of places they would like to go using public transportation. The program schedule will include meeting 1 to 2 times per week.

GPS Subgroups

In addition to being placed one of the three groups, all participants are invited to participate in a GPS subgroup. Participants in the GPS subgroups will do their intervention group activities as normal but will also be monitored through a phone with GPS tracking capabilities. This will allow us to learn more about where you use transportation in your community through GPS data. If you agree to be in a GPS subgroup and are randomly selected to participate, you will meet with a research assistant to confirm that you'd like to be in a GPS subgroup, complete a similar consent form, learn more about the directions and expectations, and receive the GPS tracking software, either through your personal cell phone or a phone loaned by the research team.

What are my responsibilities if I take part in this research?

There is a time commitment necessary for all participants, although the amount varies depending on which group you are assigned to. All participants will be responsible for completing the three interviews as well as the phone surveys in the weeks following the interviews. In addition, you will be responsible for going to intervention activities such as sessions and meetings with the peer-support specialist. Participants assigned to a GPS subgroup will have additional minor responsibilities related to their personal cell phone or the cell phone loaned to them to collect GPS data. These GPS group responsibilities will be explained to you in greater detail if you are assigned to a GPS subgroup.

What happens if I say no, I do not want to be in this research?

The alternative to participating in this study is not participating. This study is voluntary. If you decide not to take part your services will not be affected in any way. Because we randomly assign participants and don't let you choose what intervention group you're in, if you are unwilling to commit to a travel training group you are not eligible to participate in the study.

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

You have the right to drop out of this study at any time. If you choose to leave the study there is no penalty or loss of benefits to which you are otherwise entitled. Dropping out will not affect your future care. If you no longer wish to be in the study you can let us know by telling research staff in person when they are at a study site or by us at (215) 204-3257 or tucollab@temple.edu. Any de-identified data that has already been collected will not be removed from the study database when you are removed from the study and cannot be removed from any larger data sets to which it has already been added for other research. If you withdraw from the study, the

research team will stop collecting data from the KeyCard, Monthly Pass, or Indego Pass, but trip data that was collected prior to your withdrawal will not be removed from the study database.

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

In the interviews you will be asked questions about diagnoses, medication, and hospitalization, and you may find such questions distressing or triggering. You are allowed to skip any questions that you do not wish to answer and you can always stop the interview if it causes you discomfort. In addition, there are inherent risks for everyone using public transportation, biking, and travelling in the community, which may include vehicle accidents or safety risks when crossing streets. These are not risks caused by the study but are risks everyone experiences when travelling in public spaces. If you feel that you have been harmed as a result of participating in this study, you may seek care at an emergency department or from your medical provider. If you feel you need care or assistance, you may contact your own doctor and therapist as well as study personnel. Finally, there is always the risk of a loss or breach of confidentiality when personal health information is involved. To deal with this inherent risk the study team has procedures in place to prevent a loss of confidentiality, which are described in the next section.

What happens to the information collected for this research?

Study staff will protect your personal information closely so no one will be able to connect your responses or any other personal information to you. Data files are made confidential by assigning coded identification numbers to collected data and then separating these numbers from any individual identifying information. Physical copies of information are kept in locked cabinets and any electronic copies are kept in password protected files. Study files are kept for seven years after the last publication of the data. To the extent allowed by law, we limit the viewing of your personal information to people who have to review it. Federal or state laws may require us to show information to university or government officials (or sponsors) who are responsible for monitoring the safety of this study. Any information about child abuse or intent to harm self or others will be reported to authorities, as is required by law. Temple University IRB, the Philadelphia Department of Public Health IRB, and the Office of Human Research Protections are all allowed to inspect research records for this study.

To advance science, it is helpful for researchers to share the data they collect. By putting information into scientific databases, researchers can use combined data to get different or new results and learn even more about mental health. If you agree to take part in this study, the TU Collaborative may share de-identified data we collect from you with other researchers, research institutions, or databases like <http://www.ClinicalTrials.gov>. Not just anyone can access this data, and researchers who wish to study this information must be approved before they are allowed to use it. No information that could directly identify you or reveal who you are will ever be published or shared. You will not be contacted or notified about any results of this study or publications using study data. Research publications that use this study's participant data will be available online or from the Temple University Collaborative on request for personal use. After all participant enrollment has completed, the consent form will be posted online in accordance with the final rule. Sharing the consent form will not share any of your individual data or personal health information.

Can I be removed from this research without my permission?

You will be removed from the study if you appear under the influence of alcohol or illegal drugs or are hostile to research staff, intervention staff, or any of your peers in the study.

Is there a stipend/ reimbursement for this research?

If you agree to take part in this research, we will pay you \$20 at the end of each interview you complete, for a total of \$60 if you complete all 3 interviews. In addition, you will earn \$2 for each of the phone call questionnaires (National Household Transportation Survey) you complete, for a total of up to \$42 if all phone call surveys are completed. The money you earn for completed phone surveys can either be collected from a research team member at a community location within a week of the last phone call survey of that time period, or at the time of your next interview. Payments will be made in cash for in-person interviews, or virtual gift cards for Zoom interviews.

What else do I need to know about this research?

If you are injured as a result of taking part in this research, seek immediate medical care. Be aware that there is no commitment by Temple University, Temple University Health System or its subsidiaries to provide monetary compensation or free medical care to you in the event of a research-related injury.

By signing this consent form, you are not waiving any of the legal rights that you otherwise would have as a participant in a research study. Your signature on this form indicates that someone has explained this study to you and that you freely volunteer to be in this research. If you have questions about the study or a research-related injury, please contact the Temple University Collaborative at (215) 204-3257.

Signature Block for Adult Subject Capable of Consent

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

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent

GPS Subgroups

A third of the participants in each intervention group will be randomly invited to participate in a subgroup which will complete the intervention as normal in addition to providing us GPS data through a cell phone. This part of the study is explained to interested participants in greater detail at a later time if they are randomly assigned to the GPS group. If you do not wish to be considered for a GPS subgroup please indicate this below.

Initial

I am NOT interested in being considered for a GPS subgroup for this study _____

Consent to Be Contacted About Future TU Collaborative Research Studies

We're always starting new research related to community participation and may wish to contact you in the future to see if you'd like to participate in another study. If you think you might be interested in participating in additional studies by the Temple University Collaborative, please indicate this by initialing on the line below. You can amend your answer below at any time without consequence to you or your relationship with the study, Temple University, the Principle Investigators, or the study team. Consenting to be contacted about future studies does not automatically sign you up for future studies.

Initial

Yes, I agree to be contacted about future research studies.

OR

No, I do not want to be contacted about future research studies.
