RESEARCH CONSENT FORM

Basic Information

Title of Project: Preventing Mental Disorders Among Women Internally Displaced by War in Ukraine: The SHAWL Trial

IRB Number: H-45281

NCT06679114

Sponsor: National Institute of Mental Health (NIMH)

Principal Investigator: Karsten Lunze, MD, MPH, DrPH
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Study Phone Number: +380 (50) 602 39 80

Overview

We are asking you to be in a research study. A research study is an organized way of collecting information about scientific questions. This form will tell you what you should expect if you agree to be in the study. There are programs in place to make sure that investigators fulfill their obligations listed in this form.

It is your decision whether or not to join the study. We are doing the research to test an intervention delivered among displaced women in Ukraine. We are asking you to be in this study because you identify as being displaced within the past year and endorse symptoms of depression and anxiety. If you agree, you will meet privately with a member of the research team who will ask you questions about your mental health, health history, migration, and demographics. You will be asked to return in about one week to participate in a single group session called Acceptance and Commitment Training (ACT) or a single group session focusing on health promotion. ACT is designed to help you notice and accept negative thoughts, emotions, and experiences. We will ask you to complete a very brief phone assessment about 2 weeks after the group session and a longer follow up assessment in 3 months. The 3-month assessment can be completed in person or via phone. You may also be asked to participate in an in-depth interview as part of your 2-week and 3-month assessments.

You will find more information about what will happen in this study later in this form.

The main risks of being in the study are that you may feel uncomfortable with some questions about your personal background as well as a small risk of loss of confidentiality. You will find more information about risks later in this form.

You might benefit from being in the study because you might receive help to cope when you are experiencing negative emotions. You will find more information about benefits later in this form.

Purpose

The goal of this study is to determine the potential effectiveness of a single-session group therapy on preventing the progression of symptoms of depression and anxiety among displaced women.

What Will Happen in This Research Study

This research will be conducted by the Alliance for Public Health in Ukraine.

Although your participation will be in Ukraine, your data will be transferred to Boston, Massachusetts (US): Boston Medical Center/Boston University Medical Campus for evaluation with the collaborative Ukrainian-US research team.

After you agree to be in the study, you will be asked to complete a survey assessment today. You will be asked questions about your demographics, general health, mental health, medical care, exposure to potentially traumatic events, migration, and healthcare utilization. The interview will take place in person and will take approximately 45 minutes to complete.

You will be asked to return in about a week to participate in one group session of about five people with interventionists. You will either be randomized to the intervention (ACT) or control (health promotion group). Randomization means that the assignment of the group will be made at random, like flipping a coin. The assignment will be made by a computer program, not the researcher. You have a 2:1 chance of being randomized to the intervention group. These sessions will be held in your community and will last about 3 to 4 hours, including breaks. If you are randomized to the intervention arm, the interventionist will help you and your peers utilize techniques to manage uncomfortable feelings and will teach you how to respond to and refocus non-adaptive thoughts. The session will also focus on identifying life goals and values.

If you are randomized to the control arm, you will participate in a group session (about 3 to 4 hours, including breaks) focused on health promotion.

We will contact you by phone about 2 weeks after the session to ask you some questions about the group session and about your mental health. We estimate these questions to take around 20 minutes to complete. If you participated in the ACT intervention group, at this time you may also be asked to take part in an interview that will last approximately one hour. During the interview, we will ask you about your experiences during the intervention session.

We will contact you in 3 months to complete a follow-up assessment. This may be over the phone or in-person. You will be asked questions about your demographics, general health, mental health, medical care, exposure to potentially traumatic events, migration, and healthcare utilization. The interview will take approximately 45 minutes to complete. At the end of the study, you may also be asked to participate in another qualitative interview, if you participated in one at the 2-week assessment.

We will make an audio recording of the group session and qualitative interview.

You will be one of approximately 120 participants who will be asked to be in the study.

Risks and Discomforts

You may experience stress from the research assessments, as you will be asked sensitive questions regarding your mental health and history of exposure to potentially traumatic events. The risk of stress from interviews will be minimized by using trained interviewers and a standard interview process. You may be stressed by the length of the interviews (estimated 45 minutes). You will be allowed to stop at any time during the interviews to take a break and come back to complete them. You may also choose to skip any questions or stop the interview entirely.

You will be allowed to stop at any time during the interview to take a break and come back to complete it. A risk of taking part in this study is loss of confidentiality. Study records are confidential but there is a very small chance that someone outside the study could see them. Paper records are kept locked up and electronic records are in password-protected computers.

There is a small risk that you may experience psychological distress from the group session. The study team will provide resources to minimize this risk.

There may be unknown risks or discomforts involved.

If you decide that you want to stop being in the study, we ask that you let us know. If you stop early, you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get.

There is a risk to the confidentiality of your health information. We take special efforts to protect your health information, but there is a small chance of a data breach. The ways we will protect your privacy and confidentiality are described in a separate section later in this form.

Potential Benefits

You will receive no direct benefit from being in this study. It is possible that you could benefit from being in the intervention group, as it may help you cope with the experience of displacement; or from being in the control group, as you will learn about health promotion. The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in this study may help the investigators learn more about the experiences of women who have been displaced by the war in Ukraine.

Costs

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

Payment

You will receive the equivalent of 400 Ukrainian hryvnia for completing the baseline assessment and an additional 400 hryvnia for participation in a qualitative interview. You will also receive the equivalent of

600 Ukrainian hryvnia for completing the 3-month follow-up assessment and the equivalent of 200 Ukrainian hryvnia for completing the short 2-week phone assessment.

Confidentiality

We must use information that shows your identity to do this research. Information already collected about you will remain in the study record even if you later withdraw.

We will store your information in ways we think are secure. We will store paper files in locked filing cabinets. We will store electronic files in computer systems with password protection and encryption. Only the people listed later in this section will be given access to your information. However, we cannot guarantee complete confidentiality.

This study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. All studies funded by the National Institutes of Health that involve identifiable information are covered by a CoC**.** The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information that may identify you to anyone that is not involved in the research except as we describe below. Even if someone tries to get your information in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

If you agree to be in the study and sign this form, we will share information that may show your identity with the following groups of people:

- People who do the research or help oversee the research, including safety monitoring.
- People from Federal and state agencies who audit or review the research, as required by law. Such agencies may include the U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and the Massachusetts Department of Public Health.
- Any people who you give us separate permission to share your information.

If you are in immediate danger of hurting yourself at any time in the study, the study team will try to work with you on a plan to keep you safe. Because study staff will be trying to protect you, it is possible that your information will be shared with others as part of a plan for safety.

We will share research data where we have removed anything that we think would show your identity. There still may be a small chance that someone could figure out that the information is about you. Such sharing includes:

- Publishing results in a medical book or journal.
- Adding results to a Federal government database.
- Using research data in future studies, done by us or by other scientists.

We will ask everyone in the group session not to talk about the discussions outside the group. However, we can't promise that everyone will keep what you say confidential.

Use and Sharing of Your Health Information

You have certain rights related to your health information. These include the right to know who will get your health information and why they will get it. If you choose to be in this research study, we will get information about you as explained below. You authorize Karsten Lunze and study staff at Boston Medical Center, who are working on this research project, and their employees to use and disclose information concerning you and your identity, medical history, and information collected during this study for the following purpose: to help develop an intervention for delivery among displaced women in Ukraine to decrease symptoms of depression and anxiety. Such information may also be disclosed to or used by others involved in or overseeing the study including Boston University Medical Center Institutional Review Board and the study's sponsor, the United States National Institutes of Health (NIH). We share your health information only when we must. We ask anyone who gets it from us to protect your privacy. If you do not want to let us use your health information, you cannot be involved with this research study. This is because your health information is necessary to the conduct of this research. You may withdraw authorization to collect additional information about you at any time by writing to the local Principal Investigator, but information already collected may continue to be used and disclosed. This authorization has no expiration date.

NIMH Data Archive ($NIMH_{DA}$)

Data from this study will be submitted to the National Institute of Mental Health Data Archive (NDA) at the National Institutes of Health (NIH). NDA is a large database where deidentified study data from many NIH studies are stored and managed. Sharing your deidentified study data helps researchers learn new and important things about brain science more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the NDA Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the NIH who know how to keep your data safe will review each request carefully to reduce risks to your privacy. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

You may not benefit directly from allowing your study data to be shared with NDA. The study data provided to NDA may help researchers around the world learn more about brain science and how to help others who have problems with brain science. NIMH will also report to Congress and on its website about the different studies using NDA data. You will not be contacted directly about the study data you contributed to NDA.

You may decide now or later that you do not want your study data to be added to the NDA. You can still participate in this research study even if you decide that you do not want your data to be added to the NDA. If you know now that you do not want your data in the NDA, please tell the study researcher before you leave today. If you decide any time after today that you do not want your data to be added to the NDA, call or email the study staff who conducted this study, and they will tell NDA to stop sharing your study data. Once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, this is available on-line at https://nda.nih.gov.

We would like permission to store your research data for future studies. Please indicate below if you will allow that.

My research data may be stored in the NIMH Data Archive as explained earlier.
____Yes_____No

Re-Contact

We would like to ask your permission to contact you again in the future. This contact would be after your participation in the study has ended. Please initial your choice below:

____Yes_____No You may contact me again to ask for additional information related to this study.

____Yes_____No You may contact me again to let me know about a different research study.

Subject's Rights

By consenting to be in this study you do not waive any of your legal rights. Consenting means that you have been given information about this study and that you agree to participate in the study. You will be given a copy of this form to keep.

If you do not agree to be in this study or if at any time you withdraw from this study you will not suffer any penalty or lose any benefits to which you are entitled. Your participation is completely up to you. Your decision will not affect your ability to get health care or payment for your health care. It will not affect your enrollment in any health plan or benefits you can get. You will only be paid for the study activities that you complete before withdrawing.

Questions

The investigator or a member of the research team will try to answer all of your questions. If you have questions or concerns at any time, contact Oleksandra Sled at +380 (50) 602 39 80.

You may also call 617-358-5372 or email medirb@bu.edu. You will be talking to someone at the Boston Medical Center and Boston University Medical Campus IRB. The IRB is a group that helps monitor research. You should call or email the IRB if you want to find out about your rights as a research subject. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

You may also contact (+380 44) 490-5485. You will be talking to someone at the Alliance for Public Health IRB. The IRB is a group that helps monitor research. You should call or email (irb@aph.org.ua) the IRB if you want to find out about your rights as a research participant. You should also call or email if you want to talk to someone who is not part of the study about your questions, concerns, or problems.

Project Title: Preventing Mental Disorders Among Women Internally Displaced by War in Ukraine: The SHAWL Trial
Principal Investigator: Karsten Lunze

Subject: _____
Printed name of subject

By signing this consent form, you are indicating that

- you have read this form
- your questions have been answered to your satisfaction
- you voluntarily agree to participate in this research study
- you permit the use and sharing of information that may identify you as described

_____ _____
Signature of subject Date

Researcher: _____
Printed name of person conducting consent discussion

I have personally explained the research to the above-named subject (who has read this consent form) and answered all questions. I believe that the subject understands what is involved in the study and freely agrees to participate.

_____ _____
Signature of person conducting consent discussion Date

NOTE: THE PRINCIPAL INVESTIGATOR MUST KEEP THE ORIGINAL SIGNED, DATED CONSENT FORM AND MUST DOCUMENT THAT A COPY OF THE CONSENT FORM WAS GIVEN OR OFFERED TO THE PARTICIPANT

BMC and BU Medical Campus IRB
IRB NUMBER: H-45281
IRB APPROVAL DATE: 05/20/2025