

Informed Consent Cover Page

Official Study Title:

Empowering Narratives: Aid to Self-help for Ukrainian Refugees

A Randomized Controlled Trial of Narrative Exposure Therapy (NET) Delivered by Supervised Ukrainian Health Professionals in Norway

ClinicalTrials.gov Identifier (NCT Number):

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Responsible Institution:

Kristiania University College

School of Health Sciences and School of Art, Design, and Media

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Information about the research project

“Empowering Narrative: Aid to Self-Help for Ukrainian Refugees”

In this letter, we provide you with information about the objectives of this research project and what the project entails for you if you choose to participate.

Purpose

The object of this research project is to provide treatment that can mitigate trauma to refugees from Ukraine due to Russia's invasion of Ukraine in 2022. We will do this by building an intervention using narrative exposure therapy (NET); a therapy method which is based on storytelling and performing arts. We also aim to develop a methodology that allows the use of NET not only as an individual treatment tool for survivors of violence due to armed conflict, but also to create conditions for the development of a psychoeducational artistic intervention based on narratives throughout the process of individual treatment of survivors participating in the project. In other words, after the completion of each participants' individual treatment, we will anonymously use the narratives created through NET as an inspiration to build a common narrative. This common narrative will be used as basis for a performance with professional artists using dance, spoken word and music. The aim of the performance is to create a space for both participants and members of the Ukrainian population in Norway (the audience) where we can elevate and make visible the trauma of the participants. Through this it may be possible to offer NET as a community-based treatment to a larger proportion of Ukrainian refugees in Norway through art. In addition, the performance can act as a vessel to communicate the trauma of the Ukrainian refugees to mainstream Norwegian society.

Who is responsible for the research project?

This interdisciplinary research project has two institutes involved across Kristiania University College, which are all responsible for the project (data controller): School of Health Sciences and Schools of Art Design and Media.

Why have you been included in the project?

Our aim is to include sixty Ukrainian refugees as participants to receive trauma treatment through the study. You can be included in this study since you are a Ukrainian refugee living in Norway after 24.02.22 and are above the age of 18years. Only personal data you give us will be processed in this project.

What does the project mean for you?

After filling out this online consent form and giving us your contact information, you will get contacted by the research team for screening. The project starts August 20th, 2024, and ends 20th of April 2026. This means that you will receive the first step of the study, screening, within this time frame. Even so, most likely you will receive screening during the spring 2025. The screening section involves you answering some questionnaires which will map different aspects of you and your health. You will fill out these forms with the help of a supervised Ukrainian health professional in training. It will take 2–3hours to complete. Apart from general demographic information, these tests will measure your level of depression, anxiety, trauma exposure, PTSD, somatic problems, impairments

of living and grief. If you get classified as having PTSD based on the results from the questionnaires, you will randomly be assigned to one of two groups: Case group or wait list control group. If you get assigned to the case group, you will be offered to receive individual narrative exposure therapy (NET) from a Ukrainian health professional in training, supervised by an experienced NET therapist. NET is a psychotherapy intervention based on cognitive behavioral therapy, storytelling and arts, where you and your therapist will work through your life focusing on the traumatic events you have experienced. NET has been found to be a helpful treatment for people suffering with PTSD. The study will be carried out over a couple of months, and you will receive between 4–8 sessions. The number of sessions will be planned with your therapist during the first session. Each session usually lasts between 90–120 minutes. At the end of NET, you will receive your narrative created through the treatment and you and your therapist in training will discuss your narrative. Right after your last NET-session and six months after the last NET-session, you will be invited to come back to fill out the same questionnaires related to PTSD, depression, and dissociation, as was done in the beginning.

If you get assigned to the wait list control group, you will not be offered treatment right away. Six months after the screening was performed you will be invited back to fill out the same questionnaires related to PTSD, depression and dissociation, as was done in the beginning. After this you will be invited to receive NET, as explained for the first group in the section above.

Participants with diagnosis, history, or scores compatible with the psychotic spectrum will be excluded from participation in the study. If the survey of a possible participant indicates critical mental health problems in this spectrum, the person will be advised and guided to contact mental health services for appropriate treatment. The primary investigator can issue a letter communicating the scores to the general practitioner (fastlege) if requested by the excluded participant. Another exclusion criteria is participation in an ongoing psychological treatment for trauma or PTSD symptoms. In other words, if you previously registered interest in this study but at the time of NET-treatment are undergoing treatment for trauma or PTSD symptoms, it will not be possible for you to be included in this study.

With your consent, the narratives created through NET may be used anonymously in a sister-project to build a script that will be used by performing artists to build a performance which you will be invited to come see. Before then, in addition to the individual NET, you may be asked to participate in NETFacts (group intervention) where you will develop narratives together with other participants in the project who also received individual NET.

The NET exposure sessions will be recorded using video-app VISO connected to Nettskjema, which will upload directly to TSD (Services for Sensitive Data). Only your therapist-in-training's supervisor, project leader and project coordinator will have access to these recordings. The recordings will only be used for training and educational purposes for your therapist-in-training, where the therapist-in-training will get feedback from their supervisor. Recordings will be deleted right after the therapist-in-training's supervisor has seen the specific video and given commentary to the therapist-in-training.

You can object

You can object to being included in this research project at any time, and you do not have to give a reason. All your personal data will then be deleted. There will be no negative consequences for you if

you choose to object. In case you object to continue participation during the therapeutic process when you are receiving NET, you will be given the right to continue the NET therapy, but your data will not be registered and considered for research.

Your privacy - how we store and use your information.

We will only use the information about you for the purposes we have described in this letter. We treat the information confidentially and in accordance with the privacy regulations.

Only the project group will have access to your personal data. To make sure that no unauthorised persons can access your personal data, we will be using a scrambling key that will replace your name and contact details with a code. The list of names, contact details and respective codes will be stored separately from the rest of the collected data in separate places within TSD: a secure platform for collecting, storing, analysing and sharing sensitive data in compliance with the Norwegian privacy regulation. We will publish our findings, but you will not be recognized in publications. The narratives you will create through NET will only be used as an inspiration for the artistic performance.

What happens to your personal data at the end of the research project?

The information will be anonymised when the project ends, which according to the schedule is 20.04.26. However, in accordance with privacy regulations, we will store your personal data pseudonymised five years after the project has ended for documentation purposes. After these five years, all personal data will be deleted. Other collected data will be used anonymously, as stated within this consent form, for future research. Your individual narrative created through NET will also be deleted five years after the end of the project: As stated previously, the narratives created through NET will only be used as an inspiration for a manuscript for the artistic performance in the sister project, hence only the manuscript will be used in the project and stored after the end of the project for documentation purposes.

What gives us the right to process personal data about you?

We are processing information about you because the research project is considered to be in the public interest, but you have the right to object if you do not wish to be included in the project. We implement measures to protect your privacy. One of the measures is that we obtain your consent [after the Health Research Act] for your participation in the research.

On behalf of Kristiania University College, Sikt – Norwegian Agency for Shared Services in Education and Research, has assessed that the processing of personal data in this project is in accordance with the privacy regulations.

Your rights

As long as you can be identified in the collected data, you have the right to:

- object
- access the personal data registered about you
- have personal data about you corrected/rectified,
- have personal data about you deleted, and
- file a complaint with the Norwegian Data Protection Authority regarding the processing of your personal data.

If you have questions about the study, or would like to know more or exercise your rights, please contact:

- *Vanessa Nolasco Ferreira at School of Health Sciences, Kristiania University College. E-mail: VanessaNolasco.Ferreira@kristiania.no*
- *Our Data Protection Officer: personvernombud@kristiania.no*

If you have questions related to the assessment of this project by Sikt's data protection services, contact:

- Data protection services at e-mail (personverntjenester@sikt.no) or by phone at: +47 73 98 40 40.

Yours sincerely,

Vanessa Nolasco Ferreira – [Project Leader](#)

Signe Alexandra Domogalla - [Project Co-leader](#)

Ashley Rebecca Bell - [Project Coordinator](#)

Consent form

Note that even if you give consent to take part in all parts of the project below, you may at any time withdraw your consent for participation in all or some parts of the study. All people who fulfill the inclusion criteria for the project and is interested in participation, will receive screening. Based on the screening results you may be offered NET. You will be informed by the research team if you qualify for further participation, and if so, which randomized group you will be signed to. You will also have the possibility to discuss your results.

I have received and understood information about the project “Empowering Narrative: Aid to Self-Help for Ukrainian Refugees” and have been given the opportunity to ask questions. I give consent:

- To fill out questionnaires at the start (and right after treatment and six months after treatment end – if applicable) of the study treatment. These questionnaires will measure demographic data, level of depression, anxiety, trauma exposure, PTSD, somatic problems, impairments of living and grief. I consent that the results of these tests will be stored de-identified in TSD
- That my personal contact information is stored securely in TSD
- That the data from the scores of questionnaires can be used anonymously in research and publication(s)
- To receive narrative exposure therapy (NET) by a Ukrainian health professional in training. The Ukrainian health professional will treat you as part of their training, hence they will be supervised by an experienced NET therapist – if applicable
- That the narrative exposure therapy sessions will be recorded using VISO-app through Nettskjema directly connected to TSD. Only your therapist-in-training's supervisor, project leaders and project coordinator will have access to these recordings. The recordings will only be used for educational purposes for your therapist-in-training. That my narrative created through NET can be used anonymously, together with other participants narratives, to inspire a script that will create a performance through performing artists in the project's sister project – if applicable

To participate in NETFact (group intervention) – if applicable

Note: If you consent to participate in all parts of the study, check every box. You will always have the possibility to withdraw your consent.

I give consent that my personal data will be processed until the end of the project, as disclosed in this informed consent form.

(Signed by participant, date)