

## Research Protocol 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):

NCT00000000 (Replace with actual number once registered)

### Document Type:

Study Protocol – Version 4 submitted for Regionale komiteer for medisinsk og helsefaglig forskningsetikk (REK)

### Responsible Institution:

Kristiania University of Applied Sciences

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

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# Research Protocol: Empowering Narratives: Aid to Self-help for Ukrainian Refugees

## A. Project Leader

**Vanessa Nolasco Ferreira**

**Position:** Associate Professor in Psychology, School of Health Sciences, Institute of Psychology, Pedagogy and Law Kristiania University College

**Background:** Clinical psychology, with a master's in psychology and PhD in Sciences – Public Health

## B. Scientifically Designed Project Plan

### **Project Purpose and Justification**

The project aims to provide training in Narrative Exposure Therapy (NET) to Ukrainian health professionals in Norway, enabling them to offer supervised trauma treatment to Ukrainian refugees living in Norway. This project addresses the mental health impacts resulting from the Russian invasion of Ukraine, aiming to benefit directly 70–90 people from the 73,000 Ukrainian refugees in Norway.

The aim of the project is to offer training in the use of Narrative Exposure Therapy (NET) to Ukrainian healthcare professionals in Norway so that they can offer supervised treatment with NET for Ukrainian refugees. The healthcare professionals will also collect data for a pretest-posttest randomized controlled experimental study via guided practice. Data will provide an in-depth overview of the consequences for mental health after exposure to war and flight and will measure the effectiveness of treatment. The anonymized personal narratives can be used to communicate the effects of human rights violations through performing arts produced in a sister project – a psychoeducational intervention that communicates the refugees' experiences and helps to create understanding among the majority population. Høyskolen Kristiania (HK) is the project owner and collaborates with i.a. Mental Health, Universität Konstanz, NAV, Norwegian-Ukrainian aid organization and Vårsta Diakoni.

### **Materials and Methods**

The project has two main goals:

1. Offer Ukrainian healthcare personnel who moved to Norway further training in NET.
2. Treat trauma symptoms in Ukrainian refugees in Norway through guided practice

The project also provides an opportunity to integrate Ukrainian refugees into the Norwegian working life through the practice. We collect data in a pretest-posttest randomized controlled experimental study, which increases knowledge about mental health amongst refugees and contributes to a low-threshold health service becoming available to those who need it. Through this, we can build a more diverse and inclusive society.

NET is a treatment approach for PTSD as a result of organized violence or family violence. The patient is invited to repeatedly talk about the traumatic event in detail while reliving the emotions, cognitions, physiology, behavioral and sensory elements and meaning associated with the event.

With the therapist's guidance, the patient constructs a narrative that focuses on the detailed context of the traumatic experiences, as well as on important elements of the emotional networks and how they come together. This gives the opportunity to recognize that the fear/trauma structure is the result of past experiences, and that the activation is nothing more than a memory. The emotional response to the memory of the traumatic events is reduced, leading to remission of PTSD symptoms. At the same time, patients gain access to lost memories and develop a sense of connection, control and integration. As possible challenges, we expect that the participants may experience stress in the exposure therapy, this is mitigated with psychoeducation, a normalization of the symptoms during the treatment. The project manager is trained and experienced in handling such situations. A certain skepticism is also expected at the beginning of the recruitment of patients, we expect that Ukrainian healthcare professionals who carry out the training will reduce this challenge.

**The projects imply:**

1. Training Program: A digital course in NET will be developed and offered to Ukrainian health professionals.
2. Implementation: The trained health professionals will apply individual NET in Ukrainian refugees adults during supervised practice.

**Study Design:** Pretest-posttest randomized controlled experimental study.

**Data Collection:** Mental health data and demographics will be collected from participants that volunteer to participate in the study before the intervention/NET-treatment, right after the intervention and 6 months after the interventions end. Five validated instruments will to be used for measuring and mapping demographics and mental health including trauma, PTSD and depression. These five instruments are named: 1) Demographic questions, 2) PHQ-9, 3) LEC-5, 4) The International Trauma Questionnaire (ITQ), 5) and SHUT-D. These instruments are also available without copyright in Russian and Ukrainian, and these will be used in cases where the participant needs/wants them in their native language instead of English. Please note that the participant will not fill out these questionnaires themselves, they will always be filled out in the form of an interview by the health professional in the training program or researcher/project-participants.

The participant in the study will be tested for chronic mental health problems before the actual intervention (NET) takes place. In this way, participants with diagnosis, history and / or scores compatible with the psychotic spectrum will be not included 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 fastlege (general practitioner). Another exclusion criteria are participation in an ongoing psychological treatment for trauma and / or PTSD symptoms. In other words, in case a person registered interest in the study and are undergoing this type of treatment at the time of the intervention taking place, it will not be possible to include this person in the study. Right after the NET-treatment has been completed, the participants/patients will fill out the majority of the same forms/questionnaires/instruments as done before NET-treatment took place and have a follow-up 6 months after the therapy has finished with the same instruments/questionnaires. In this way, the effect of the treatment can be measured. These results will also be able to be published anonymously on a group level to see whether NET influenced PTSD symptoms. It is important to highlight that the method (NET) is based solely on the narratives of the participants themselves: If the patient refuses to share their narratives, this decision will be respected and supported. Participants that withdraw consent to participate in the study will have the right to continue the treatment with

NET as planned/offered by the study. The only change is that their data will not be included in the study.

### **Study Design and Timelines**

The project starts with the development of a digital course in NET to be offered to Ukrainian healthcare personnel living in Norway (responsibility VNF, SAD, AK, LA, SA, JM, SB). Mapping of healthcare personnel interested in joining will take place at the same time with the help of our collaboration with NAV (responsibility OF, CT and OB). In July 2024, VNF and ARB will apply to REK and SIKT for a project concerning a pretest-posttest randomized controlled experimental study. From November 2024 to January 2025 (change to accommodate time to get approval from REK), the course will be offered to between 20 and 30 healthcare personnel (responsibility VNF, SAD, AK, LA, ARB, SA, SB). From January 2025, Ukrainian healthcare personnel will have supervised practice (VNF, AK, SA, EB, JV). They will practice screening the mental health of potential participants and the use of NET in participants who meet the inclusion criteria for this type of therapy (VNF, SA, AK are responsible). At the same time, the research and data collection also start. HH and SW will be responsible for randomization and quantitative method. VNF, as primary investigator, will be responsible for data collection and data processing in accordance with all the ethical guidelines and the Declaration of Helsinki. The guided practice and data collection will take place until November 2025. The data analysis will start in May 2025 and will continue until March 2026. This activity will take place at the same time as the data collection (VNF, SAD, ARB, HH, SW, AK, LA, FS, NO will function in this activity, VNF is mainly responsible). Between March and April 2026, the final report will be constructed. This shows our and the health personnel's evaluation of the course, which data has been collected and the analysis of this data, as well as how the project can possibly be continued for other user groups (VNF, SAD and JM are mainly responsible for the report).

## **C. Health Information Handling**

### **Sources and Management**

- Sources: Data will be collected from Ukrainian health professionals and refugees participating in the study through informed consent and voluntary participation
- Data Transfer: Data will be securely stored using TSD (Services for Sensitive Data) and handled per ethical guidelines.
- Clarification about video recording: Video recordings (with audio) will only be used for training purposes in the individual session when using and will be deleted as soon as the need is no longer there. VISO will be used to make video recordings and be directly connected to TSD (<https://www.uio.no/tjenesters/it/adm-app/nettskjema/hjelp/viso.html>). Only the main project participants (Vanessa Nolasco Ferreira, Ashley Rebecca Bell and Signe Alexandra Domogalla) and the NET supervisor for the individual participant's therapist will have access.

To clarify the recording routine: The recording made of each session is deleted after each completion. The reason that recordings must be made is because the course takes place digitally online, so the recording should act as a learning opportunity for the course participant/health worker. The supervisor of each course participant is the only one who will watch this recording (and probably only a fraction, approx. 15min +/-) in order to be able to provide valuable feedback to course participants on their practice in supervision (course participants and course supervisors). After supervision, recordings related to the sessions that were commented on in the supervision will be permanently deleted from TSD. Course participants will not have access to the recording, only the individual course supervisor as well as project managers and project coordinator (for security reasons).

- Data Sharing: No health information will be transferred outside the EEA.

## D. Handling of Human Biological Material

### Sources and Management

Not applicable as this project does not involve collecting human biological material.

## E. Ethical Considerations

### Ethical Challenges and Risk-Benefit Assessment

- Risks: Participants may experience stress during exposure therapy, mitigated by psychoeducation and symptom normalization.
- Benefits: Participants are expected to experience reduced PTSD symptoms and improved mental health. The training will enable Ukrainian health professionals to integrate into the Norwegian workforce, fostering a diverse and inclusive society.
- Ethical Approval: Ethical approvals will be sought from REK (Regional Committees for Medical and Health Research Ethics) and SIKT (Norwegian Agency for Shared Services in Education and Research).

## F. Funding Sources, Interests, and Dependencies

<b>INNETEKTER</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>TOTAL:</b>
Inntekter DAM	109000	270000	18000	397000
Egne midler Kristiania	102047	599446	69100	770593
Offentlige midler	0	0	0	0
Andre inntekter	0	0	0	0
SUM INNETEKTER:				1167593

<b>UTGIFTER</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>	<b>TOTAL:</b>
Lønn og sosiale kostnader	161047	699446	87100	947593
Innkjøp av tjenester/honorar	50000	150000	0	200000
Materiell/utstyr	0	20000	0	20000
Andre utgifter	0	0	0	0
SUM UTGIFTER:				1167593

The project is funded by the Dam Foundation and supplemented by internal resources from Kristiania University College.

## G. Plan for Dissemination of Results

- Scientific Publications: Articles in academic journals, presentations at conferences.
- Public Outreach: Articles in popular science media, reports to public authorities, and a book or e-book documenting the project.

- Digital Media: Project websites, podcasts, and social media channels.
- Commercial Use: Potentially expanded use of research results and educational materials for broader applications.

## I. Emergency Procedure

The preparedness procedure involves two possible measures that the participant is offered in case of signs of Complex PTSD and / or moderately severe or severe depression. 1) A psychoeducational conversation with the associate professor Vanessa Nolasco Ferreira who has expertise as a clinical psychologist. The purpose is to normalize the psychological symptoms, but also to encourage the participant to take the symptoms seriously. 2) Participants are also offered the possibility that the primary investigator issues a letter addressed to the fastlege (general practitioner - GP) informing on the screening scores so that the GP can follow up the person's mental health. These procedures are optional, and the participant must agree orally to one or both offers.

The emergency procedure is triggered when the scores for measure PTSD / complex PTSD shows severity, based on the frequency, intensity, severity and in PHQ-9 the scores are equal or superior than 15-27 (that shows moderately severe or severe depression), or if the participant answers 2-3 (More than half of the days; Almost every day) on question 9 of the PHQ-9 depression scale: "Thoughts that it would be better if you were dead or about harming yourself".


## J. Guideline: Treatment options for participants who do not qualify for NET

These guidelines will be further elaborated closer to the time of the study/data collection. Offers change continuously, and we will inform any participants about the health services available at the time via a letter like this. We will also contact these health services in advance and get a confirmation of whether it is okay to recommend their health services to our participants (who do not qualify for the study):


- Fastlege
- Rask helsehjelp: <https://www.oslo.kommune.no/helse-og-omsorg/helsetjenester/psykisk-helsehjelp/rask-psykisk-helsehjelp/#gref>
- Mental helse: <https://mentalhelse.no/fa-hjelp/hjelpetelefonen>


## K. Final Approval REK


PROJECT





**Styrkende narrativ: Hjelp til selvhjelp for ukrainske flyktninger**  
Title translation to English: Empowering Narratives: Aid to Self-help for Ukrainian Refugees

**PROJECT MANAGER**  
[Vanessa Nolasco Ferreira](#)  
at Kristiania University College

**PROJECT OWNER / COORDINATING INSTITUTION OR UNIT**  
Kristiania University College

**APPROVALS**  
Regional committees for medical and health research ethics - 790305

**CATEGORIES**  
HEALTH PROJECT TYPE  
Other study

**TIMELINE**  
Active

Available on the website: <https://app.cristin.no/projects/show.jsf?id=2726408>