UNIVERSITÉ DU LUXEMBOURG

December 10, 2025

RESEARCH PROTOCOL FOR THE PROJECT

FOSTERING UKRAINE'S CAPACITY IN DELIVERY AND RESEARCH OF INNOVATIVE EVIDENCE-BASED PTSD TREATMENT

SECTION 1: PROJECT

Title:	*Fostering Ukraine's capacity in delivery and research of innovative evidence-based PTSD treatment*
Acronym:	*Lux4UA*

Applicant(s):

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Funding:

Source:	*FNR under LUXAID BRIDGES CALL*

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SECTION 2: SHORT SUMMARY OF THE PROJECT
(including research design and methodology)

*The **Lux4UA Project**'s goal is to foster Ukrainian mental health professionals' capacity in transdisciplinary research on innovative, evidence-based trauma treatment (Reconsolidation of Traumatic Memories (RTM) Protocol) in humanitarian emergencies due to war and displacement. To accomplish this goal, the RTM Protocol Effectiveness and Feasibility studies will be conducted.*

***The RTM Protocol effectiveness study** implies a randomised field trial comparing RTM with treatment-as-usual (Trauma-Focused Cognitive Behavioral Therapy (TF-CBT), Eye Movement Desensitization and Reprocessing (EMDR), or pharmacotherapy) across three customary clinical settings in Ukraine (hospital in-patient, hospital out-patient, private psychotherapy). The primary outcome is the loss of Post-Traumatic Stress Disorder (PTSD) diagnosis or change in symptoms; secondary outcomes include depression and anxiety at post-treatment, 6 m and 12 m follow-up.*

***Objective 1:** To compare the effectiveness of the RTM Protocol for the treatment of trauma-related mental conditions with other evidenced-based trauma-focused therapies (TF-CBT, EMDR and medication).*

***Objective 2:** To investigate the effectiveness of the RTM Protocol for the treatment of trauma-related mental conditions in different settings of mental health (MH) care (inpatient and outpatient hospital care for veterans and private psychotherapy for civilians)*

***The RTM Protocol and Training feasibility study** will evaluate the RTM Protocol's acceptability and adaptability during training and practice through case statistics, satisfaction surveying of MH practitioners and clients, and focus-group interviews with MH practitioners.*

***Objective 1:** To analyse the acceptability of the RTM Protocol among MH professionals and persons with trauma-related MH conditions)*

***Objective 2:** To analyse the adaptability (Usability of the Ukrainian language versions) of the RTM Protocol*

Data will be collected, pseudonymised in Ukraine by implementing partners - the Centre of Mental Health and Rehabilitation "Forest Glade" of the Ministry of Health of Ukraine (RCFG) and the National Psychological Association of Ukraine (NPAU), and transferred in fully anonymised, aggregated form to the University of Luxembourg for analysis. Findings will inform humanitarian response policy and sustainable capacity-building for evidence-based PTSD treatment in low-resource, conflict settings.

SECTION 3: AIM OF EACH OF THE STUDIES

Study No.	Aim	Study will involve: *Please tick all appropriate boxes*
Study 1: *The RTM Protocol effectiveness study*	*To compare the effectiveness of the RTM Protocol for the treatment of PTSD with other evidenced-based trauma-focused therapies (TF-CBT, EMDR and medication) in different settings of MH care accustomed for Ukraine (inpatient and outpatient hospital care for war veterans and psychotherapy for civil trauma survivors).*	☒ Human participants ☒ Vulnerable population ☐ Human biological material ☐ Pre-collected biological material ☒ Personal data ☐ Pre-collected personal data ☐ risks on the environment ☐ risks on the society
Study 2: *The RTM Protocol and Training feasibility study*	*To analyse the acceptability of the RTM Protocol among MH professionals and persons with PTSD and the adaptability of the RTM Protocol & RTM Training for the country context.*	☒ Human participants ☒ Vulnerable population ☐ Human biological material ☐ Pre-collected biological material ☒ Personal data ☐ Pre-collected personal data ☐ risks on the environment ☐ risks on the society

Please expand the rows in case of additional studies.

SECTION 4: DETAILS OF EACH STUDY

Study 1: The RTM Protocol Effectiveness Study

Target sample size: (Please justify the target sample size, either statistically or by referring to existing literature)	*The research sample for the **EFFECTIVENESS STUDY** is expected to be 120 participants (people with PTSD), approximately equally distributed between experimental and control groups (at least 20 participants).* *The sample expectancy is based on case numbers estimated by every MH care provider involved in the Project. The allocation ratio was calculated based on the assumption that the mean of PCL-5 would be 25.0 for the control group and 21.0 for the experimental group (SD of 3.0); a type 1 risk is 5.0%, and a type 2 risk is 20.0%, for the bilateral test and a dropout rate at 20.0%, the minimum N of participants in each group should be equal to 12.*
Key inclusion criteria:	*Key inclusion criteria for the effectiveness study participants are (1) being adults ≥ 18 years, (2) having a diagnosis of PTSD determined by DSM-5-TR or ICD-11 and/or (3) having PTSD symptoms causing clinically significant distress or impact on social, occupational, or other areas of functioning defining on base of using PTSD Checklist PCL-5, (4) being resident of Ukraine.*
Key exclusion criteria:	*Key exclusion criteria for the effectiveness study participants are (1) having any other acute comorbid mental health conditions, (2) receiving any other parallel PTSD treatment, (3) being unable to provide informed consent, has severe cognitive impairment, or is otherwise unlikely to adhere to study procedures.*
Age range of participants:	*Adults aged 18-65.*
Country/ies of recruitment:	*Ukraine*
Expected duration of procedure:	*Data collection will occur at baseline (diagnostic session), 1 month after complete treatment application, in 6 months (follow-up booster session), and in 12 months (second follow-up booster session) and will take approximately 15 min each, 45 min per person.*
Data Collection:	*Paper questionnaires, digital entry; no audio/video.* *Data on age, gender, veteran and IDP statuses, residency, type of trauma, medical diagnosis and symptoms, scores from PCL-5 (for PTSD), PHQ-9 (for depression), GAD-7 (for anxiety) diagnostic scales will be collected from printed questionnaire sheets filled in by participants.* *PTSD diagnosis will be collected from medical records.* *Names, email-address, phone number will be collected from printed informed consent.* ***Data transfer.** Aggregated, fully anonymised raw data will be shared by implementing partners' coordinators through Zenodo under closed access and using the EUSurvey Platform (an online survey-management*

	system developed by the European Commission) only with PI Viktoriia Gorbunova.
Methodology:	***Research design**. The RTM Protocol effectiveness study implies a randomised field trial comparing RTM with treatment-as-usual (TF-CBT, EMDR or pharmacotherapy). It is chosen and will be standardised based on CONSORT 2010 Statement: reporting parallel group randomised trials. To enhance the external validity of the findings, all the interventions are planned to be explored among three different settings of mental health care accustomed to Ukraine: mental health hospital care (inpatient and outpatient care for veterans) and psychotherapeutic practice (for civil trauma survivors).* ***Measures.** Primary outcome effectiveness measures are MH professional proved existence or loss of PTSD diagnosis and/or PTSD symptoms severity measured by PTSD Checklist PCL-5 (re-experiencing of trauma, avoidance of trauma-related stimulus, negative alterations in cognition and mood, hyper-arousal).* *Among secondary outcome measures will be the existence and severity of depression and anxiety-related symptoms according to PHQ-9 and GAD-7 scales.* ***Data analysis.** Descriptive Statistics: means, SDs, medians, frequencies and percentages, baseline comparability between groups (t-tests, chi-square tests). Primary and Secondary Outcome Analysis: mixed-effects repeated measures ANOVA. Handling Missing Data: multiple imputation or maximum likelihood estimation under MAR assumption. Effect Size Reporting: Cohen's d, odds ratios, and 95% confidence intervals.* *Data collection will be in Ukrainian language (all the scales are validated in Ukrainian and recommended by the World Health Organisation for the screening of the mentioned mental health conditions) at baseline (diagnostic session), 1 month after complete treatment application, in 6 months (follow-up booster session), and in 12 months (second follow-up booster session).*

***Study 2:** The RTM Protocol and Training Feasibility Study*

Target sample size: (Please justify the target sample size, either statistically or by referring to existing literature)	*The research sample for the **FEASIBILITY STUDY** is expected to be 20 participants according to the trauma-related cases/workforce availability ratio of implementing partners: 10 persons from each site.* *The number of clients is expected to be 60 persons (persons treated with the RTM Protocol) according to the RTM Protocol effectiveness study description.*
Key inclusion criteria:	*Key inclusion criteria for MH professionals are (1) holding an accomplished higher education degree in the mental health area (psychology, psychiatry, psychiatric nursing, clinical social work), (2) having at least three years of hands-on clinical experience in mental-health settings, (3) being formally trained to deliver mental health care*

	to people exposed to trauma through accredited coursework, supervised practice, or equivalent, (4) meeting Ukrainian licensing and registration requirements mandated by health-care regulations and the implementing organisation's internal policies, (5) committing to attend the full training, complete all associated supervision sessions, and deliver the Protocol as specified by the study timeline. *The client sample is the same as for the study 1.*
Key exclusion criteria:	*Key exclusion criteria for MH professionals are (1) being under investigation, suspension, or other disciplinary action by a professional body or employer, (2) lacking mandatory professional continuing education for the last year (min 40 hours), (3) having caseload exceeding the threshold for service quality requirements (> 30 active therapy clients).* *The client sample is the same as for the study 1.*
Age range of participants:	*Adults aged 18-65 (with regard to the eligibility criteria).* *The same sample as for the study 1.*
Country/ies of recruitment:	*Ukraine*
Expected duration of procedure:	*MH Professional will be engaged into case statistic collection (30 min per case, 1 hour per person); satisfaction surveying (15 min per person) and focus-group interviews (1,5 hour of group work).* *Clients will be engaged into satisfaction surveying (15 min per person).*
Data Collection:	*Intervention Usability Scale, satisfaction survey; audio-recorded focus-groups interviews.* *Data on MH professionals' occupation, place of work, professional experience, trauma-centred methods used; data from Intervention Usability Scale and case statistics (number of trauma-related requests, trauma-specific cases treated with the RTM, hours spent for each case treatment, process comfort, expected and reached results, usefulness for different types of trauma and trauma-related symptoms), will be collected from printed questionnaire sheets filled in by participants.* *Data on MH professionals' Protocol use features, implementation benefits and challenges, effects and consequences, clients' acceptance and perception will be collected and audio-recorded during focus-group interviews.* *MH professionals' names, email-address, phone number will be collected from printed informed consent.* *Data on clients' treatment satisfaction (process comfort, expected and reached results, usefulness for client's types of trauma and trauma-related symptoms) will be collected from printed questionnaire sheets filled in by participants.*

	Clients' names, email-address, phone number will be collected from printed informed consent. ***Data transfer**. Aggregated, fully anonymised raw data will be shared by implementing partners' coordinators through Zenodo under closed access and using the EUSurvey Platform (an online survey-management system developed by the European Commission) only with PI Viktoriia Gorbunova.*
Methodology:	***Research design**. The RTM Protocol and Training feasibility study will evaluate the RTM Protocol acceptability and adaptability during training and practice through case statistics, satisfaction surveying of MH practitioners and clients, and focus-group interviews with MH practitioners. As a standardisation base for the feasibility study the Framework for the development and evaluation of complex interventions issued by the National Institute for Health and Care Research (NIHR) was chosen.* ***Measures.** To assess the RTM Protocol's acceptability by MH professionals, case statistics such as the number of trauma-related requests, trauma-specific cases treated with the RTM, hours spent for each case treatment, etc., will be collected. The standardised Intervention Usability Scale will also be applied.* *Also, satisfaction with the procedure and therapeutic process from both sides (clients and MH professionals) will be surveyed regarding process comfort, expected and reached results, usefulness for different types of trauma and trauma-related symptoms, etc.* *MH professionals' feedback will also be considered during the focus-group analysis. The focus-group protocol and script will be developed with input from every implementing partner to match the local frame of mental health care. The script previews topics such as the RTM Protocol use features, the RTM Protocol implementation benefits and challenges, the RTM Protocol effects and consequences, the RTM Protocol clients' acceptance and perception, etc.* *The RTM Protocol's adaptability will be measured by analysing the case statistics and MH professionals' feedback for the Ukrainian version of the protocol.* ***Data analysis**. For Quantitative Analysis will be utilised descriptive statistics (frequencies, means, SDs for usability and satisfaction scores), correlation analysis (between usability scores and satisfaction or case outcomes (e.g., Spearman's rho)).* *Qualitative Analysis will be conducted using thematic analysis (transcripts coded using inductive and deductive approaches, themes mapped to NIHR framework domains), charting and mapping.*

SECTION 5: RISK ASSESSMENT AND RISK MINIMIZATION

Study 1: The RTM Protocol Effectiveness Study

Potential risk(s)	***Extent of risk(s) and measures taken***
Human participants are involved in the study with potential risk related to ☐ Physical harm ☐ Psychological harm ☒ Invasion of privacy ☐ Social and economic harm ☐ Other	*Personal data will be collected (see data collection section).* ***Data collection measures**. Implementing partners' coordinators will collect data using printed versions of questionaries (which will be destroyed after data e-input and prior this time they will be stored in a secure storage cabinet).* *Mental health professionals involved in the research will collect data on clients (people with PTSD) using clinical scales which will be destroyed after data e-input and before it will be stored in a secure storage cabinet.* ***Data Storage measures**. The e-data will be stored on encrypted hard drives and will be accessible only to implementing partners' coordinators. They will create password-protected access to the data with the help of the organisations' IT departments.* ***Data Pseudonymization measures**. The data will be pseudonymized by the implementing partners' coordinators and professionals involved in the research for the purpose of follow-up assessments using European Data Protection Board Guidelines on Pseudonymisation, 2025.* *Usage and storage of personal data will fully comply with Ukrainian legislation, the Civil Code of Ukraine, and the Law of Ukraine on the Protection of Personal Data.* *No mentioned non-anonymized personal data will be used for the research purposes, transferred or processed in Luxembourg.*
Are there any specific risks to the human participants involved, if any.	*Risk of adverse effects is usually considered in studies on mental health interventions. It is important to mention that possible adverse effects are minimised by the RTM Protocol procedure itself, which is focused on processing traumatic events without triggering emotional hyperarousal by quick termination of every therapeutic technique at first sign of client' distress. Nevertheless, clients' support will be organised according to existing procedures and requirements of mental health care established by the implementing partners (RCFG, NPA) and through adverse-effect management and reporting that aligns with safety requirements of the CONSORT-Harms 2022 framework.* *Adverse-effect management includes the following measures:* ***- anticipating adverse effects** (PTSD symptoms deterioration; emotional distress);* ***- adverse effects monitoring & detection** (using implemented into the Protocol assessments procedures as measurement of subjective distress and physiological arousal calibration, as*

	well as additional monitoring with the PCL-5 (for PTSD), PHQ-9 (for depression), and GAD-7 (for anxiety) diagnostic scales); *- **mitigating adverse effects** (terminating the intervention, utilizing grounding and "break state" techniques, referring for other types of help and support, providing extra visits, crisis referrals, and medication);* *- **recording every episode of adverse effects** in patient documentation;* *- **reporting adverse effects** to the site coordinator for processing and reflection in study reports and publications.* *No mentioned project activities will be executed in Luxembourg or with Luxembourg or EU residents.*

***Study 2:** The RTM Protocol and Training Feasibility Study*

Human participants are involved in the study with potential risk related to ☐ Physical harm ☐ Psychological harm ☒ Invasion of privacy ☐ Social and economic harm ☐ Other	*Personal data will be collected (see data collection section).* ***Data collection measures**. Implementing partners' coordinators will collect data using printed versions of questionaries (which will be destroyed after data e-input and prior this time they will be stored in a secure storage cabinet) and focus-group interviews audio-recordings with following transcription. Mental health professionals involved in the research will collect data on clients (people with PTSD) using printed versions questionaries which will be destroyed after data e-input and before it will be stored in a secure storage cabinet.* ***Data Storage measures**. The e-data will be stored on encrypted hard drives and will be accessible only to implementing partners' coordinators. They will create password-protected access to the data with the help of the organisations' IT departments.* ***Data Pseudonymization measures**. The data will be anonymized by the implementing partners' coordinators.* *Usage and storage of personal data will fully comply with Ukrainian legislation, the Civil Code of Ukraine, and the Law of Ukraine on the Protection of Personal Data.* *No mentioned non-anonymized personal data will be used for the research purposes, transferred or processed in Luxembourg.*
Are there any specific risks to the human participants involved, if any.	*There are no anticipated specific risks for the human participants.*

SECTION 6: DATA PROTECTION

Study 1: *The RTM Protocol Effectiveness Study*

The Project PI will have access only to aggregated, anonymised data. The implementing partners' coordinators and professionals involved in the research will collect, pseudonymise (for the purpose of follow-up assessment in two weeks, six months, and one year), and anonymise the clients' data. Implementing partners' coordinators will aggregate the data and input it on the EUSurvey Platform (an online survey-management system developed by the European Commission) to transfer it to Luxembourg. The transferred data will be stored on the University of Luxembourg-protected server ATLAS for up to 10 years.

Pseudonymisation and Coding Strategy will be based on the European Data Protection Board (EDPB) Guidelines on Pseudonymisation, 2025.

The study design requires pseudonymisation only for follow-up post-treatment assessments for PTSD symptoms severity (PCL-5), existence and severity of depression (PHQ-9), and anxiety-related (GAD-7) symptoms at 2 weeks, 6 months, and 12 months post-treatment. The main purpose is to enable linkage of repeated assessments while restricting direct identification.

It is planned to have 3 experimental groups in 3 different treatment settings (Hospital Inpatient, Hospital Outpatient, Psychotherapeutic Practice) and 3 control groups with "treatment-as-usual" in the same three types of settings, with 20 participants each. It creates 6 study samples with 120 participants in total. Each participant will receive a unique study participant ID (PID) upon inclusion, generated as: [GroupCode]- [SettingCode]- [SequentialNumber]. For example, ExpHIP001: Experimental group, Hospital Inpatient setting, Participant 1.

Enrolment and randomisation (steps taken at baseline and immediately after each enrolment). As soon as a participant is enrolled, the site coordinator assigns a sequential number, allocates the study sample using Randomisation Software, and creates a PID. The coordinator writes down the PID on each paper document for follow-up contact and records the PID on the pseudonymization key list uploaded to the NPA/ RCFG staff laptop/desktop (encrypted hard drives).

Data collection (before and during follow-up assessments). Whenever data are gathered later, the research staff involved (therapists, assessors, or other professionals) manually write each participant's PID on every paper document related to that follow-up contact, allowing the data to be linked back to the correct person without revealing their identity.

For the follow-up post-treatment assessments (2 weeks / 6 months / 12 months), sites' coordinators will use the secure key to retrieve participant contact from the PID. Re-assessment tools will be administered with the same PID. Results will be stored again using a pseudonym only.

Study 2: *The RTM Protocol and Training Feasibility Study*

The Project PI will have access only to aggregated anonymised data (professionals-participants' occupation, place of work, duration of professional experience, trauma-centred methods used, data from satisfaction surveying, Intervention Usability Scale and focus-group interview etc.) Implementing partners' coordinators will collect, anonymise, aggregate the data and input it on the EUSurvey Platform (an online survey-management system developed by the European Commission) to transfer it to Luxembourg. Focus-group interview transcripts' transfer to Luxembourg will be done through Zenodo under closed access. The transferred data will be stored on the University of Luxembourg-protected server ATLAS for up to 10 years.

Comments on the possible misuse of the research:

The Lux4UA project is designed exclusively to evaluate the effectiveness and feasibility of the RTM Protocol. It does not aim to collect prevalence data, epidemiological statistics, or any form of population-level surveillance. All data are collected solely for the purpose of assessing therapeutic outcomes and implementation feasibility within predefined clinical settings.

No new diagnostic tools are being developed, and no data will be used to infer broader mental health trends or conditions across populations. The study samples are limited, purposive, and context-specific, selected based on clinical availability. Therefore, the findings cannot be extrapolated to estimate prevalence or inform policy beyond the scope of treatment evaluation.

Furthermore, the project does not involve any form of geolocation, behavioral tracking, or longitudinal profiling beyond anonymized follow-up assessments. All data are pseudonymized and aggregated before analysis, and no individual-level identifiers are retained or transferred.

Given the sensitive context of war and displacement, we acknowledge the theoretical risk of misinterpretation or misuse of mental health data. To mitigate this, the project adheres strictly to ethical guidelines from EFPA, CIOMS, and the IASC, and all implementing partners operate under national ethical oversight. The research outputs will be framed explicitly within humanitarian and clinical care contexts, avoiding any language or framing that could be construed as diagnostic surveillance or military profiling.

We also commit to transparency in dissemination: all publications will include clear disclaimers about the scope and limitations of the data, and no data will be shared with third parties outside the research consortium.

Data storage

	Raw data *(incl. video or audio recordings)*	*Processed data* *(anonymized, pseudonymized)*	*Document(s) containing the names, contact information and personal details (the pseudonymisation key list)*	*Other material*
Data carrier (digitalized or paper form)	*Paper questionnaires* *Focus-group interview audio-recordings.*	*Excel files with fully anonymised data exported from EUSurvey Platform* *Word files with fully anonymised data transcripted from focus-group interview audio-recordings.*	*Informed consent forms, pseudonymization key list.*	
Number of copies	*Paper questionnaires for each client, 120 copies; for each MH professional, 40 copies.* *Focus-group interview audio-recordings, 1 copy for each implementing partner.*	*Numbers required by the needs of analysis, 1 copy for each type of data.*	*Informed consent forms for each client, 120 copies; for each MH professional, 40 copies.* *Pseudonymization key list, 1 copy for each site.*	
Storage Location	*Paper questionnaires are stored in locked cabinets at the sites' locations in Ukraine.* *Focus-group interview audio-recordings are stored locally on encrypted hard drives of implementing partners.*	*EUSurvey Platform (for data collection); ATLAS server (for data analysis and storage); Repository Zenodo (under closed access for data transferring; under open-access repository for open-access publications); Repository ORBilu (for open-access publications)*	*Informed consent forms are stored in locked cabinets at the sites' locations.* *Pseudonymization key lists are stored locally on encrypted hard drives of implementing partners.*	
Retention period	*Paper questionnaires will be destroyed after digital entry.*	*on EUSurvey Platform for 1 year; on ATLAS for up to 10 years; on Zenodo for the repository's lifetime, on ORBilu for the repository's lifetime.*	*Identifying data will be deleted 5 years following end of research project.*	

Data access

Data collection. *Implementing partners' coordinators (Tetiana Sirenko from the RCFG, Valeriia Palii from the NPA) will collect data on MH professionals using printed versions of questionnaires and focus-group interviews audio-recordings with the following transcription. All the data will be destroyed after data digital entry (made by coordinators) and prior to this time they will be stored in a secure storage cabinet and on encrypted hard drives.*

Mental health professionals involved in the research will collect data on clients (people with PTSD) using printed versions of questionnaires and clinical scales, which will be destroyed after data digital entry (made by coordinators) and prior to this time they will be stored in a secure storage cabinet.

Data Storage. *The e-data will be stored on encrypted hard drives and will be accessible only to implementing partners' coordinators. They will create password-protected access to the data with the help of the organisations' IT departments.*

Data Pseudonymization. *The implementing partners' coordinators (Tetiana Sirenko from the RCFG, Valeriia Palii from the NPA) will pseudonymize the data for follow-up assessments.*

Data sharing. *Aggregated, fully anonymised raw data will be shared by implementing partners' coordinators (Tetiana Sirenko from the RCFG, Valeriia Palii from the NPA) through Zenodo under closed access and using the EUSurvey Platform (an online survey-management system developed by the European Commission) only with PI Viktoriia Gorbunova.*