

Research Protocol

Complex-Posttraumatic Stress Disorder in Urban Egypt: Cultural Adaptation and Pilot Testing of an Evidence-Based Treatment Manual

Pilot Registration Protocol

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11th June 2024

Table of Contents

Glossary of abbreviations	3
Project summary	4
1. Current state of research: Background and rationale	5
1.1. Complex PTSD	5
1.2. Cultural variation in CPTSD	5
1.3. Cultural and Structural Considerations in CPTSD Diagnosis	6
1.4. Culturally adapted interventions for CPTSD	7
1.5. Study setting: Egypt	7
2. Project Aims	8
3. Methodology	8
3.1. Study Design	8
3.2. Research team & collaborations	9
3.3. Ethics approvals	9
3.4. Study Intervention: Enhanced STAIR.....	9
3.5. Diagnostic module.....	10
3.6. Target population & recruitment.....	10
3.7. Pilot study procedures	10
3.8. Withdrawal & discontinuation	14
3.9. Outcome measures	14
3.10. Data Analysis	15
3.11. Handling of missing data & dropouts.....	16
4. Ethical Considerations	16
4.1. Risks	17
4.2. Benefits	17
4.3. Risk Management	Error! Bookmark not defined.
4.4. Adverse Events	17
4.5. Guidelines and regulations	18
4.6. Amendments.....	19
5. Data management and protection	19
5.1. Data recording.....	19
5.2. Confidentiality and retention	19
5.3. Data protection agreement UniL/AUC.....	20
6. Pilot registration	20
7. Results management / Publications	20

8. Funding.....	20
9. Declaration of interest.....	20
10. Time plan overview	21
11. Expected outcomes & relevance	21
12. References.....	22

Glossary of abbreviations

<i>AUC</i>	<i>American University in Cairo</i>
<i>ANOVA</i>	<i>Analysis of Variance</i>
<i>CA-CBT</i>	<i>Culturally Adapted Cognitive Behavioural Therapy</i>
<i>CAPMAS</i>	<i>Central Agency for Public Mobilization and Statistics</i>
<i>CFI</i>	<i>Cultural Formulation Interview</i>
<i>CPTSD</i>	<i>Complex post-traumatic stress disorder</i>
<i>DESNOS</i>	<i>Disorders of Extreme Stress Not Otherwise Specified</i>
<i>DSO</i>	<i>Disturbances in self-organisation</i>
<i>DSM</i>	<i>Diagnostic and Statistical Manual of Mental Disorders</i>
<i>ESTAIR</i>	<i>Enhanced Skills Training in Affective and Interpersonal Regulation</i>
<i>eCRF</i>	<i>electronic Case Report Form</i>
<i>FGD</i>	<i>Focus group discussions</i>
<i>GAD</i>	<i>General Anxiety Disorder Questionnaire</i>
<i>GCP</i>	<i>Good Clinical Practice Standards</i>
<i>HRA</i>	<i>Human Research Act</i>
<i>HRO</i>	<i>Ordinance on Human</i>
<i>ICD</i>	<i>International Classification of Diseases</i>
<i>ITI</i>	<i>International Trauma Interview</i>
<i>ITQ</i>	<i>International Trauma Questionnaire</i>
<i>LMIC</i>	<i>Low and Middle Income Countries</i>
<i>MENA</i>	<i>Middle East and North Africa</i>
<i>NGO</i>	<i>Non-governmental organization</i>
<i>OCFI-R</i>	<i>Outline for Cultural Formulation Interview – Revised</i>
<i>PHQ</i>	<i>Patient Health Questionnaire</i>
<i>PTSD</i>	<i>Post-traumatic stress disorder</i>
<i>RCT</i>	<i>Randomised controlled trials</i>
<i>RECAPT</i>	<i>Reporting Criteria for Cultural Adaptation of Psychological Interventions in Clinical Trials</i>
<i>SIDES</i>	<i>Structured Interview for Disorders of Extreme Stress</i>
<i>STAIR</i>	<i>Skills Training in Affective and Interpersonal Regulation</i>
<i>STARC</i>	<i>Skills-Training of Affect Regulation–A Culture-sensitive Approach</i>
<i>SSS-8</i>	<i>Somatic Symptoms Scale</i>
<i>TF-CBT</i>	<i>Trauma-Focused Cognitive Behavioural Therapy</i>
<i>UniL</i>	<i>University of Lausanne</i>
<i>WHO</i>	<i>World Health Organization</i>
<i>WMO</i>	<i>Medical Research Involving Human Subjects Act</i>

Project summary

Background: The CPTSD diagnosis presented in the ICD-11 is supposed to provide core and culturally invariant symptoms, which is supported by recent research. Yet, evidence also shows the necessity of integrating culture-specific symptoms in intervention and diagnostic tools to enhance the validity and efficacy of such diagnoses and therapeutic interventions. Along with cultural aspects, there are relevant structural aspects e.g., economic, and social inequalities, which impact mental health. These aspects remain understudied in low middle income countries like Egypt, where there are considerable rates of violence. **Aims:** Our project aims to i) culturally adapt and pilot test the therapeutic manual ESTAIR/MPE in urban Egypt, and ii) to pilot test a cultural and structural module for the diagnostic assessment of CPTSD among the same target population. The primary outcomes are the feasibility, acceptability of both the manual and diagnostic modules. The secondary outcome is to assess the manual's initial impact on clinical outcomes. **Methods:** Following the RECAPT criteria, in earlier phases, our project gathered qualitative data from key informants on the cultural and structural dimensions of CPTSD in urban Egypt. Using the collected data, we are currently culturally adapting this intervention. Subsequently, we will pilot-test it in four groups of five participants each. We intend to collect both quantitative and qualitative measures to explore determined outcomes and analyze them accordingly. This protocol is submitted to obtain ethical approvals for the pilot testing phase of the study. **Expected results:** The project will be the first to adapt a therapeutic program for CPTSD in the Middle East and Northern African (MENA) region. The adapted ESTAIR manual will be validated in later clinical trials. Results can be generalised and utilised in MENA countries and with refugee populations in high-income countries.

1. Current state of research: Background and rationale

1.1. Complex PTSD

In 2018, the International Classification of Diseases (ICD-11) introduced the CPTSD diagnosis [1]. CPTSD is a sister diagnosis of post-traumatic stress disorder (PTSD). Its symptoms develop as a result of extreme, recurrent, or chronic traumatic experiences that are difficult or impossible to escape, such as interpersonal trauma, child abuse, political violence, torture, or imprisonment [2]. For a CPTSD diagnosis, PTSD symptom clusters (i.e., intrusions, avoidance, and hyperactivation) must be met, and three additional symptom clusters summarised as "disturbances in self-organisation" (DSO) must be fulfilled [3]: affective dysregulation; negative self-concept; and disturbances in interpersonal relationships [2, 4, 5] causing severe functioning impairment.

The new CPTSD diagnosis was developed with the aim of providing the core symptoms that are invariant across cultural groups [6]. Over time, substantial quantitative evidence emerged from various cultural contexts indicating that this aim has been met, and that the core symptoms of CPTSD are applicable in a variety of cultural contexts [7-12]. The distinction between PTSD and CPTSD has been demonstrated in more than 10 studies testing its factorial structure in clinical and non-clinical samples in the UK, USA, Denmark, Austria, Germany, Israel, Bosnia, Uganda [6], Eastern Asian countries [7], among three community samples in Nigeria, Kenya, and Ghana [12], as well as among traumatized refugees [11]. The two-factor structure (PTSD and CPTSD) was confirmed across 33 studies worldwide [13].

At present, there are two assessment tools available for diagnosing Complex Post-Traumatic Stress Disorder (CPTSD) based on the diagnostic criteria outlined in the ICD-11. These tools are the International Trauma Questionnaire (ITQ, Cloitre et al., 2018), and the International Trauma Interview [ITI, 14]. The ITI is the clinician-administered interview version of the ITQ. In an effort to be consistent with the principles of ICD-11, which aim to optimize the clinical utility and global relevance of the diagnostic criteria by focusing culturally invariant core symptom clusters [1], both assessments include only 12 items, with two items assigned to each symptom cluster. The tools also assess functional impairment. Currently, the ITQ has been validated in multiple cultural contexts, while the validation of the ITI is still underway in several other European countries.

1.2. Cultural variation in CPTSD

At the same time, evidence also shows that there might be some degree of cultural variation in certain features of the symptomatology of CPTSD [15, 16]. The ICD-11 Working Group on the Classification of Disorders Specifically Associated with Stress acknowledged this evidence. Although there is large consensus on PTSD and CPTSD core features, the working group stated that there might be some degree of cultural variation in the on the symptom-level presentation of these disorders [5].

These findings are aligned with results from the field trials of the diagnosis 'Disorders of Extreme Stress Not Otherwise Specified' [DESNOS, 17], the CPTSD predecessor, which was introduced to in Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV, 18]. In a study examining the the cross-cultural validity of the DESNOS concept across three post-conflict samples in Algeria, Ethiopia, and Gaza, using the Structured Interview for Disorders of Extreme Stress [SIDES, 19]. Results showed that the factor structure of the SIDES was not stable, indicating that the theoretical concept of DESNOS was not the same across the three samples. In addition, they found that some features were less prevalent in the studied samples than in other DSM-IV trials conducted in Western countries.

Based on these results, the authors proposed "the construction of a universal core module to capture the consequences of extreme stress across cultures, with local modules that fit culture-specific expressions of extreme stress" [20, p. 20]. In this context, they also proposed distinguishing

three different types of symptoms: core symptoms that are the same across cultures (type A), symptoms that are unique to a culture but reflect universal underlying problems (type B), and expressions of culture-specific processes that have specific symptoms (type C). The authors suggested including type B and C symptoms in local modules.

As mentioned earlier the newly developed CPTSD diagnosis was developed with the aim of providing the core symptoms that are invariant across cultural groups (type A), and has so far been successful in achieving this aim. Thus, quantitative research indicates that CPTSD as a diagnostic construct is valid across different cultural groups, and that the core symptoms of CPTSD are applicable cross-culturally. What remains to be done is more ethnographic research to define what de Jong, Komproe [20] considered as type B and C symptoms.

In a conceptual review, Heim et al [21] highlight a lack of evidence, and important research implications concerning the cultural variations within the DSO. While they concur the universality of the overall diagnostic criteria of CPTSD, they suggest that the way these symptoms present themselves may vary according to cultural background [22]. Examples of such cultural variations include differences in: emotion expression and regulation [23, 24]; or negative self-related emotions such as shame and guilt [25, 26]; and the nature of interpersonal relationships [27, 28]. To address this literature gap our team has conducted two systematic review of qualitative studies of PTSD, CPTSD, and DSO in the greater MENA region, and in Sub-Saharan Africa [29, 30]. Major findings of these reviews confirm previous literature findings in cultural variations of the DSO features, with further providing more detailed accounts of such variations and underlying cultural assumptions, and at times effects of structural factors.

1.3. Cultural and structural considerations in CPTSD diagnosis

Thus, more qualitative evidence on culture-related information on DSO symptoms is needed, as recommended by the ICD-11 Working Group on Cultural Influences [15] to inform and enhance culturally congruent diagnosis and interventions for CPTSD. Such qualitative evidence on cultural variations in DSO symptoms related need to be used to construct local cultural modules, which include the type B and C symptoms. Researchers in various cultural contexts have already started working on the validation of culture-specific modules for other specific mental disorders, e.g., prolonged grief disorder [31, 32], depression, and anxiety [33, 34]. Current research from Asia, Africa, and Latin America shows that by adding culture-specific symptoms to standardized assessments, diagnoses become more valid and accurate [e.g., 21, 33].

Another way to include cultural specific symptoms and idioms is to use the cultural formulation approach presented in the Cultural Formulation Interview (CFI) in the DSM-5 [35]. This interview gives respondents the opportunity to address cultural distress idioms, illness explanatory models (cultural explanations), and treatment expectations in their assessment process. The revised version of the CFI, labeled the Outline for Social and Cultural Formulation (OSCF), allows clinicians to include structural aspects related to distress symptoms [36].

Recent evidence points to the importance of including structural and social determinants of mental health, such as socioeconomic inequalities, unemployment, availability of social networks or support, among others, for more valid diagnoses and to provide more relevant and effective therapeutic interventions [36, 37]. Such structural aspects have largely been neglected in clinical case formulation previously. Investigating ongoing structural and socio-political violence is important because it significantly contributes to mental disorders and impaired functioning and enhances risks of other forms of interpersonal violence such as intimate partner violence [38]. In including structural factors, clinicians, understand the interplay between cultural dimensions and clinically relevant social and structural constraints and provide more accurate formulations and management of psychopathology [36, 37].

1.4. Culturally adapted interventions for CPTSD

Over the past decade, culturally adapted manuals for the treatment of PTSD have been developed, which include interventions to improve emotion regulation strategies among culturally diverse populations [e.g., 39, 40], yet these manuals do not target DSO symptoms of CPTSD specifically.

Hence, at the moment, there are no validated treatments for CPTSD containing therapeutic elements for all three features of the DSO globally [41]. Recent findings show that multicomponent interventions, i.e., the ones that combine trauma-focused cognitive-behavioral interventions with elements to work on the DSO, showed promising results among Western samples of survivors of child sexual abuse [41-43]. Moreover, dropout rates were lower for such multicomponent interventions than for standard PTSD manuals. The flexibility offered by the multiple components or modules allows for more room for cultural adaptation to address the needs of diverse cultural populations [44]. One program, the Skills Training in Affective and Interpersonal Regulation with Modified Prolonged Exposure (STAIR/MPE) [45], which focuses on improving emotion regulation and interpersonal problems, showed good effects among survivors of child sexual abuse in the US [46]. The STAIR/MPE manual has since been expanded to cover the full symptomatology of CPTSD in a limited number of sessions (23 sessions). This complete manual (enhanced STAIR/MPE) has not yet been validated and accordingly has not been published.

Recent meta-analyses of randomised controlled trials (RCTs) highlight the importance of culturally adapting interventions, reporting significantly higher effects on symptom reduction when comparing adapted interventions to non-adapted active treatments [47, 48]. When executed thoroughly, culture adaptation ensures the inclusion of ideographic cultural information of a particular cultural group, thus increasing acceptability and efficacy, while also maintaining the structured format of evidence-based therapeutic manuals [49]. Our project aims to culturally adapt and pilot the ESTAIR manual. This is a first and very important step in providing a disorder-specific therapeutic manual to a cultural group that differs from Western populations for which most manuals have been developed.

1.5. Study setting: Egypt

Against this background, our study will be set in Egypt, where there is elevated risk of relevant traumatic exposure for multiple reasons: high poverty rate (28%) [50, 51]; high levels of domestic violence, with over 30% of women reporting different forms of abuse (physical, emotional, or sexual) [52]; and corporal punishment as a disciplinary method (37% of children) [53]. The country is also currently going through unprecedented economic hardships [54]. The aftermath of the 2011 revolution had a significant impact on violence exposure, including political clashes, sexual violence, mob societal violence, and governmental crackdown on any political or civil activity with 106,000 political detainees since 2011 and numerous torture accounts [55, 56].

Egypt's historical and cultural heritage overlaps with that of other countries in the Middle East and North Africa (MENA). Egypt shares cultural background with other Arab nations and has a similar colonial history as other North and Sub-Saharan African countries. [55, 56]. In addition to exposure to violent incidents, the urban population in Egypt faces continuous structural difficulties. Other studies in low- and middle-income countries (LMIC) have shown elevated rates of interpersonal and structural violence in similar settings [57, 58]. Scholars make the point that the prolonged, continuous, and inescapable forms of violence, such as those experienced in Egypt, may result in complex trauma [17]. The specific cultural and structural setting in Egypt makes this study very relevant and allows it to offer promising implications.

Similar to other countries in the region, psychological distress in Egypt is exacerbated by high levels of stigma related to mental disorders [59]. Egypt also has very limited mental health resources and access to such resources is compromised by lack of funding and a lack of culturally relevant training of

professionals [60]. Consequently, there is a pressing necessity for the development and adaptation of effective treatments to address the specific needs of Egypt and other MENA populations and consider both cultural and structural factors faced by them.

2. Project aims

The specific aims of our project are the following:

1. To culturally adapt and pilot test the ESTAIR/MPE therapeutic manual among individuals exposed to prolonged violence in urban Egypt, with the objective of gathering more detailed information about its feasibility, acceptability, and initial impact in clinical outcomes for later scientific validation.
2. To pilot test a local diagnostic module for CPTSD, which includes type B and C symptoms that are specific to our target population, as well as questions for assessing structural factors contributing to this disorder.

Our primary outcomes are the feasibility, acceptability of the adapted ESTAIR manual and diagnostic module.

Our secondary outcomes are the initial impact of the manual on clinical outcomes (i.e. CPTSD, depression, anxiety, somatic symptoms, and wellbeing). Please see section 3.10 and 3.11.

3. Methodology

3.1. Study design

This is a mixed-method, multi-phase study. We will follow the newly established Reporting Cultural Adaptation in Psychological Trials (RECAPT) criteria, which were developed to enhance rigour and transparency in cultural adaptation processes [54]. The RECAPT criteria include three phases. Phase 1 includes conducting a systematic review to summarise the current state of research. Phase 2 entails conducting formative qualitative fieldwork to collect relevant information. Phase 3 includes the cultural adaptation and pilot testing of the ESTAIR manual.

Phase 1 Literature review:

A systematic review on qualitative studies of PTSD, CPTSD, and DSO in the greater MENA region has been completed by the research team at UniL and published [53].

Phase 2 Formative research:

Data collection for phase 2 was conducted from July 2023 till February 2024. Please refer to previously approved protocols for further details.

Phase 3 Cultural adaptation & pilot study:

We will conduct an uncontrolled pilot study to evaluate the feasibility and acceptability of the culturally-adapted ESTAIR therapeutic manual for the treatment of CPTSD in urban Egypt. Additionally, we will assess the feasibility and acceptability of incorporating a cultural diagnostic module into the ITI to evaluate CPTSD symptomatology in the same population.

Using pre- and post-assessments, we will examine the potential impact of the interventions on psychopathology, specifically CPTSD, depression, and anxiety, while also evaluating the effects on

well-being. Due to the lack of control in the study design and insufficient statistical power, it will not be feasible to draw any conclusions regarding the efficacy of the intervention.

The detailed procedure of phase 3 are presented in this protocol.

3.2. Research team & collaborations

This project is a part of a larger research consortium in Switzerland working with other universities and governmental and non-governmental organisations (i.e., University of Zurich, the Swiss Red Cross in Berne, and the Appartenances Association) to carry out a parallel study among refugees resettled in Switzerland. Thus, the methodology will be the same. Both projects are supervised by Prof. Dr. Eva Heim. The team also includes three PhD students, including NH, at the University of Lausanne. The Egypt project will be done in close collaboration with the Department of Psychology at the American University in Cairo [54]. Dr. Kate Ellis will be a collaborator in this study. AUC has already approved this collaboration and has issued NH a visiting researcher status effective January 2023, renewed in January 2024, and renewable for the duration of the project (see Appendix 1 for host institution invitation letter).

3.3. Ethics approvals

All ethics approvals for phase two (formative research) have been granted by the Institutional Review Board of AUC (No. 2022-2023-277) and the Ethics Committee at the Faculté SSP at UniL (No. E_SSP_062023_00001).

This current protocol is submitted to obtain ethical approval for phase three (pilot phase). Applications are submitted to both AUC and UniL's ethical review committees for approval. AUC's Institutional Review Board acts as the designated local ethics committee and ensures that all studies are implemented according to Egyptian laws and directives.

To the best of our knowledge, given the small scale of this pilot study and incorporation of qualitative data no further approvals are needed from the Central Agency for Public Mobilization and Statistics, CAPMAS, Egypt.

3.4. Study intervention: Enhanced-STAIR

Results from the formative research, along with team discussions and decisions, were documented and are being used in adapting the ESTAIR manual. This includes all cultural adaptations, as well as adaptations to take structural factors into account. A template based on the RECAPT criteria will be used to record all adaptations throughout the project. Several model studies have used this template [61-64] in close collaboration with the project supervisor, Prof. Eva Heim.

ESTAIR is a psychotherapeutic manual for the treatment of CPTSD. It contains 25 sessions that are organized in 4 modules, targeting the CPTSD symptom categories. In addition to an introductory session, which include psychoeducational material, the manual contains three other modules to address the DSO symptoms clusters. The included modules are as follows: emotion regulation (5 sessions), self-concept (6 sessions), and relationship difficulties (5 sessions). Module 4 (5-7 sessions) is based on narrative reprocessing, which helps treat PTSD symptoms. Afterwards, there is one final session covering relapse prevention and a summary of the work. The manual concludes with a relapse prevention/closure session. Please find in Appendix 3 an overview of ESTAIR manual sessions.

The manual will be translated into Egyptian Arabic to facilitate use during therapy. After the final adjustments are made based on the pilot findings and patient feedback, the manual will be further modified accordingly.

3.5. Diagnostic module

The ITI is a clinician administered diagnostic interview used to evaluate the symptoms of PTSD and CPTSD. The interview consists of 12 items/questions pertaining to the six symptom clusters that characterize these two disorders, as outlined by the ICD-11 [14]. A diagnosis requires the presence of at least one indicator for each symptom, as well as functional impairment. The original ITI will be implemented, in addition to a recently created cultural and structural module. Please see Section 3.8 Procedures.

Data collected during the formative stages is being used to develop the cultural diagnostic module for this population and other Arabic-speaking populations with similar cultural and structural conditions in the MENA region. The cultural module will include context-specific symptoms that have been identified in our formative research. We have also developed a structural difficulties list based on the OSCF-R [36] that has been adapted to LMIC based on our field interviews in Egypt, which include difficulties such as financial stressors, social role and status, difficulties accessing services (e.g., health, education), and perceived discrimination, or safety concerns. As previously mentioned, structural factors have a direct impact on symptomatology of stress related disorders [36, 65, 66]. It is expected that added components will enhance the instrument's validity and render a more valid diagnosis. Please refer to Appendix 5 for the full ITI and the cultural module draft.

3.6. Target population

Our target population is Egyptian adults living in urban settings, i.e., major cities in Egypt. Egypt is a large, heavily populated, and diverse country, challenges encountered by urban populations may significantly differ from those faced in rural areas. Literature from LMIC show that urban environments are characterized by increased violence rates and limited healthcare resources [67]. As we aim to have our diagnostic module and therapeutic manual to be culturally and structurally sensitive, we thought that focusing on urban population will allow us to include more contextual variables thereby making the intervention more targeted and relevant.

The adapted manual will be piloted with 20 participants. We aim to recruit an equal number of male and female participants. However, this number may change since women seek help more than men in Egypt [68]. Given that the project is time-bound due to funding reasons and the progression of this PhD project, recruitment should be concluded by August 2024. This short time frame might limit our ability to make extra efforts to include additional male participants.

Patients are included if they are 18 years of age or older, can give written or oral consent, are literate, have a history of severe and/or prolonged trauma, and screen positive for CPTSD. The therapeutic program will take place in Cairo, however participants are allowed to join if they reside in any other major city, if they wish. They will be excluded if they present an imminent risk of suicide, psychotic symptoms, and/or severe alcohol and/or drug abuse, or have been in therapy before (i.e., completed more than 5-10 sessions of psychotherapy).

3.7. Setting

Screening and therapy sessions will either be conducted in: 1. AUC campuses (New Cairo and Downtown); or 2. Due to Cairo's significant size and transportation difficulties, to better accommodate our participants, we are in the process of establishing ties with private clinics located in areas such as Mohandessin and Zayed, which are far from the AUC campuses. If they show their willingness to cooperate and contribute to the project, we will utilize their facilities for the purpose of conducting therapy sessions if needed. This is also for heterogeneity and inclusiveness purposes, as we want to include participants from different backgrounds and from different socioeconomic urban settings i.e. different neighbourhood in Cairo.

3.8. Pilot study procedures

Recruitment & prescreening

Our sample will be recruited from multiple settings, including referrals from MHPs in private and public settings, social media outlets, via calls for participation through university announcements, and local NGOs.

Participant will be recruited using a convenience sampling strategy [69]. Given the sensitivity of this population exposed to violence and potentially associated stigma, convenience sampling might facilitate recruitment. More importantly convenience sampling is recommended in such exploratory projects to ensure flexibility needed to make ‘real-time judgements’ during fieldwork regarding changes needed in sample characteristics or size [70].

Participants will be contacted by the applicant for phone prescreening call. Ethical guidelines recommend that phone prescreening may be conducted to determine specific inclusion and exclusion criteria and is allowed before obtaining consent. We use phone screening, for the purpose of not wasting participant’s time, and given transportation difficulties in Cairo. During the phone screening call, participants will be:

- introduced to the researcher.
- told how long the phone call is expected to take.
- informed that a set of questions will be asked to determine eligibility of the nature and sensitivity of the questions.
- asked whether there might be a better time for them to answer these questions.
- If they agree to conduct the phone call at this moment or suggested another time to be re-contacted, they will be asked if they had experienced violence for a long period of time.
- pre-screened on the phone using the PCL-5, which consists of 20 PCL-5, a diagnostic tool with 20-items to assesses the symptoms of PTSD (See Section 3.10 Outcome measures). A score above 23 suggested a provisional diagnosis of PTSD in another Arabic-speaking sample [71]. No additional identifying information will be asked and no official record of scores will be kept or connected to the participant in anyway. The same procedure was conducted in another pilot study in a trauma-focused online therapy program in Egypt [72]. Participants who score over 23 will be sent the consent sheet via the contact information they provided and invited for a study information and screening session.

Screening & informed consent

Screening interviews will be conducted by the applicant (NH), who is also a psychotherapist and practices under the licence of Maadi Psychology Center in Cairo, Egypt. During this interview additional inclusion criteria questions (i.e., immediate risk of suicide, acute psychosis, severe alcohol, or drug abuse) will be asked. Additionally, participants will be asked if they have been in therapy before or are currently in therapy. If patients are not eligible or do not want to participate, they will be referred to other treatment pathways and public and private facilities in Cairo. We have provided a list of available and trusted service providers or facilities (emergency services and outpatient services; please see Appendix 6).

NH will then explain the study information in detail and respond to the participants’ questions. This part of the session will resemble an “onboarding session,” in which the content of the manual and the study procedures will be explained more in detail. They will be informed that if they participate in the study, they will receive a standardized group therapy following a manual that includes 18-25 sessions. They will be informed of the study design, and the difference between therapy sessions and assessment

and feedback sessions. Please see below sections of procedures details. They will also be notified that therapy is provided at no cost and that their time for feedback interviews will be compensated. (For more information on compensation, please see below). They will be informed about their voluntary participation and the possibility of withdrawal at any time.

If the participant still agrees to participate, they will be asked to sign the informed consent form. Please see Appendix 2 for consent forms. As per guidelines, the participant would have had time to read the consent form sent to them prior to coming to the screening session to have more than 24 hours before consenting. We will retain the consent form as part of the study records.

Participants will then be asked to fill self-report questionnaires. Please see Section 3.10 for outcome measures. Patients will be given the option to either complete the self-report questionnaires themselves, or, if they prefer to have the therapist read the items to them. If the participant screens positive for CPTSD using the ITQ. They will then be informed that they are eligible and asked to join our study. If they agree to join, we will collect socio-demographic data, i.e., sex, age, religion, marital status, education, occupation, income.

Participants will receive compensation of 700 EGP for this session.

Cultural module-ITI pilot

At the end of this interview, patients who have screened positive for CPTSD will be asked if they are interested in participating in two formulation sessions to pilot the ITI and the cultural and structural module (please see Section 3.5). This question will be asked to participants whether they are interested in joining our therapy program or not. These sessions will be conducted independently of the screening and therapy process. Participants will be informed that their decision will not impact their inclusion in the therapeutic program and will be reminded that they have the right to decline. They will be reminded about their voluntary participation and the possibility of withdrawal at any time. They will be given a separate consent sheet and will also be informed that their time will be compensated. Please see appendix 2 for consent forms.

NH will conduct the ITI (original version and additional items of the cultural and structural module), to assess the feasibility and cultural applicability of the added module. She will be trained along with the UniL team to conduct the clinical interview. ITI formulation sessions will be audio recorded for research purposes. We will record sessions to use them to collect idioms of distress, free-listed symptoms, and cultural norms as a part of the ethnopsychological portion of this study, which will allow us to further adapt the diagnostic module and the therapy in the future. We did not conduct interviews with patients during the formative research phase (only mental health professionals, and family members/close ones of individuals exposed to violence). This was due to the high vulnerability of our population, as it would have been unethical to cause distress through interview questions without providing a treatment option.

Participants will then be invited to a debriefing interview to provide us feedback on the ITI, including the module. Feedback interviews will be conducted by a (master-level) RA and will be audio-recorded. Please see Appendix 8 for sample patient feedback interview guide; provided are guides in English, once finalized guides will be translated in Arabic.

Participants will receive compensation of 700 EGP per session, for a total of three sessions (two ITI sessions and one feedback session).

Therapeutic program

The first three modules will be provided in a group, face-to-face setting in either AUC campus or other clinics (see Section 3.7). Due to clinical reasons, Module 4 (narrative exposure) needs to be delivered individually. Module 4 will take 5-7 sessions. Hence, due to budget constraints, only 5–10 participants will be chosen to complete the narrative exposure therapy component. We will ask participants if they are interested to conduct additional 4 sessions to enhance PTSD symptoms. We will ask one group at a time until the desired number is fulfilled.

It is expected that individuals who do not undergo the narrative exposure therapy module will still experience positive outcomes from the remaining components of the intervention, including improvements in symptoms of complex PTSD and overall functioning.

Participants will be divided into four groups. Each group will consist of five participants. Groups will be organized based on geographical preference of therapy and/or participant characteristics (e.g. gender or education level) to enhance group harmony and cohesiveness. Two psychotherapists, the applicant (who is a trained psychotherapist herself), and another psychotherapist, will be trained on using the manual and will lead group sessions. They will be assisted by two master-level psychotherapists in training. The graduate program committee in the counselling psychology program AUC agreed that two master's students could serve as co-facilitators as a part of their clinical internship.

Supervision: During the 18-week intervention, weekly preparatory and peer-supervision meetings will be held. In-training therapists will have weekly supervision with Dr. Kate Ellis from AUC faculty. The whole team will also receive supervision from an experienced psychiatrist and psychotherapist with over 10 years of clinical and supervision expertise in third-wave cognitive-behavioral therapy modalities in group and individual formats (twice a month). This supervision model and team triangulation method ensure the quality and appropriateness of the intervention, as well as the ethical conduct of the students throughout their participation.

Following each therapeutic module, participants will complete an assessment including all outcome measures (see Section 3.10). Assessments will be conducted by either therapists or co-facilitators. Participants will also participate in a short qualitative interview in group format to provide their feedback on each module of the manual. Feedback interviews will be conducted by graduate (master-level) RAs. Initial baseline assessments will be administered by NH, who possesses a Citi training certificate, during the months of July and August. The T1, T2, and T3 assessments, which will be carried out by an RA(s), will not commence until September 21st 2025. Recruitment of the RAs has not yet taken place; however, it is scheduled to occur within the next month. After the recruitment of the RA, they will complete the Citi training and subsequently provide their certificate to the IRB prior to commencing any assessment activities. Please see Appendix 8 for sample patient feedback interview guide for module 1 & 2; provided are guides in English, once finalized guides will be translated in Arabic. Feedback focus groups will be audio recorded. For each assessment and feedback session participants will receive 700 EGP as compensation.

Therapists and co-facilitators will fill out a fidelity check form after each session, to retain information regarding the implementation, process evaluation, and acceptability of the intervention. Please see Appendix 4 for the fidelity form. Based on these forms, RAs will then conduct debriefing focus group discussions with therapists and co-facilitators after each module. Feedback from patients and therapists, will be used to make final adaptations in the adapted ESTAIR manual.

Therapists and RAs costs are covered by the Prix CADOT funding. MA-level therapists in training cannot be paid as their work will count towards the hours they need to fulfill in their degree.

We provide below two tables with the weekly progression plans of the pilot study:

3 module plan:

Week	0	1	2-6	6	7-12	12	13-17	18	19
Visit	Study information & pre-assessment	Introduction session	Module 1	Intermediate assessment 1/Feedback	Module 2	Intermediate assessment 2/Feedback	Module 3	Final Session	Post-assessment/Feedback

4 module plan:

Week	0	1	2-6	6	7-12	12	13-17	17	18-24	25	26
Visit	Study information & pre-assessment	Introductory session	Module 1	Intermediate assessment 1/Feedback	Module 2	Intermediate assessment 2/Feedback	Module 3	Intermediate assessment 3/Feedback	Module 4 (individual therapy)	Final session	Post-assessment/Feedback

3.9. Withdrawal & discontinuation

Participants can withdraw at any time during the interviews, without providing any reason. It is also expected in such trials that participants will drop out with giving notice.

In the event of an immediate threat of suicide or the presence of severe psychotic symptoms, participants will be removed from the study. Should these symptoms appear, the therapy will be suspended, and the participants will be guided by therapists towards appropriate services to facilitate the required clinical measures for recovery, such as crisis intervention, medication, and, if deemed necessary, hospitalization. See Section 4.2 in adverse events and see appendix 6 for emergency services list. In such cases the case of the participant will be discussed in team supervision meetings, which include a consultant psychiatrist, 2 clinical psychologists, and 3 counselling psychologists).

Data collected until that time point will be used, unless the participant requests destruction of his data.

Participants will be substituted if they drop out early (i.e. before the introductory group session before module 1 sessions begin).

3.10. Outcome measures

Questionnaires

Pre-screened: For pre-screening the 20-item self-report measure that assesses the 20 DSM-5 symptoms of PTSD. The measure is commonly used to screen for PTSD and has been used in a similar pilot study in Egypt [72]. It has also been validated in an Arabic-speaking country [71]. Please see Section 3.7 procedure for pre-screening process.

For clinical outcomes: The ITQ will be used for the assessment of CPTSD symptoms. The ITQ assesses 12 symptoms (6 for post-traumatic stress disorder and another 6 for disturbances in self-organisation). A diagnosis of CPTSD requires the endorsement of at least one of the two symptoms from each of the three PTSD symptom clusters described above (i.e., re-experiencing in the here and now, avoidance, and sense of current threat) and at least one of the two symptoms from each of the three Disturbances in Self-Organisation (DSO) clusters (i.e. affective dysregulation, negative self-concept, and

disturbances in relationships). Items are scored on a Likert scale ranging from 0 (not at all) to 4 (extremely). The endorsement of a symptom item is defined as a score ≥ 2 .

We will also include assessment tools measuring other relevant secondary outcomes, using culturally validated assessments such as the Patient Health Questionnaire (PHQ-9) [73] for depression. The PHQ-9 score may range from 0 to 27, since each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day). Higher scores mean higher levels of depression. We will use the General Anxiety Disorder Questionnaire (GAD-7) [74] for anxiety. The GAD-7 score may range from 0 to 21, since each of the 7 items can be scored from 0 (not at all) to 3 (nearly every day). Higher scores mean higher levels of anxiety. For somatic symptoms we will use the Somatic Symptoms Scale (SSS-8). The SSS-8 score may range from 0 to 32, since each of the 8 items can be scored from 0 (not at all) to 4 (severely). Higher scores mean higher levels of somatic symptoms [SSS-8, 75]. Finally, for well-being we will use the WHO-5 Wellbeing Index [76]. Scores range from 0-25, based on a Likert scale from 0 (not at all) to 5 (all of the time) for each item. Higher scores reflect better levels of well-being.

All measures have been validated in Arabic speaking samples. We will collect demographic information (e.g., sex, age, religion, education, occupation, income) from participants for possible correlations. Please find all questionnaires in English and Arabic in Appendix 7.

Qualitative feedback interviews

For acceptability outcomes: We will conduct feedback qualitative interviews after each module and overall feedback on therapy process at the end of therapy. Participants are asked about their experiences with the content and implementation process of the manual. As an example, Interview template for Module 1 and 2 can be found in appendix 8.

3.11. Data Analysis

Statistical analysis plan

For primary outcomes: We will primarily assess feasibility by determining the percentage of participants who complete the study until the end (among those who sign the informed consent). Based on reported dropout rates from studies using similar modular interventions with trauma survivors, we will consider 80-90% participation and adherence as excellent, 70-80% as satisfactory, and 60-70% as acceptable [42, 77].

We will assess the ITI feasibility, using the same method based on the percentage of participants who complete the ITI; 80-90% participation and adherence is considered as excellent, 70-80% as satisfactory, and 60-70% as acceptable.

In addition, we will calculate the mean and standard deviation of completion rates to offer more detail into the variation in adherence.

For secondary outcomes: Descriptive statistics will be calculated for demographic information and baseline characteristics of participants. For clinical outcomes, we will analyze changes in PTSD symptomatology and other clinical outcomes (e.g., depression, anxiety, somatic symptoms, and well-being) at the four or five measurement points depending on group allocation. (See section 3.8 procedures). We will use intermediate assessments after each module to statistically describe the participants' state (means, standard deviations, correlations), enhancing our understanding of the effects of intervention components.

Next, we will use pre-post comparisons based on data from the first and last assessments to establish the status of change (clinically significant change) for each participant. We will conduct one-

sided paired measures Student's t-tests at the group level. The null hypothesis (H0) is that the change is zero. The alternative hypothesis (H1) is there will be a decrease in symptoms of CPTSD, depression, anxiety, and somatization; and an increase in rates of wellbeing. Student's t tests will be conducted with a significance level of 0.05. If the assumptions for the Student's t test are not satisfied, we will utilize non-parametric tests, specifically the Wilcoxon test for paired measurements.

We will perform longitudinal analyses utilizing multilevel linear models. This will enable us to gain a deeper understanding of how participants' progress throughout the duration of psychotherapy. The multilevel models will enable us to examine the impact of additional variables, such as gender, type of trauma, or group allocation (i.e., number of sessions), in an exploratory manner.

Considering our limited sample size of 20 participants and the fact that similar interventions have shown an effect size of 0.24, we acknowledge that the lack of statistical power may prevent us from observing the effects of our intervention on clinical outcomes.

Statistics will be conducted by the same team that conducted the analysis of the parallel Swiss arm of the study (see Section 3.2 Research Team) and will be facilitated by the free software R [78]

Qualitative analysis

We will use framework analysis to extract the most important information related to acceptability from patient and therapists qualitative interviews [79]. We will use MAXQDA software to facilitate analysis [80]. Data will be transcribed and translated in Arabic by the applicant and research assistants, who are native speakers.

3.12. Handling of missing data & dropouts

Given that this is an uncontrolled pilot study, its principal aim is to assess the feasibility and acceptability of the ESTAIR manual. We will therefore closely monitor dropout rates and conduct follow-up with individuals who withdraw from the intervention. During follow-ups we will also try to encourage participants to continue treatment. We will also conduct feedback interviews, when possible, with drop-outs, to understand reasons for dropout and have accurate representation of the feasibility and acceptability of our intervention.

Regarding statistical analyses, we will not be imputing missing data. Only participants who underwent assessment at both the pretest and post-test will be included in the analysis.

4. Ethical Considerations

Our participants are from a highly vulnerable population. This will require culturally sensitive and clinically trained professionals. To anticipate this, our research team consists of local experts, such as Dr. Kate Ellis, who is highly experienced in trauma care clinical settings, as well as researchers. We also have Dr. Ahmed Abdelkarim, who has over 10 years of training professionals and experience working with vulnerable populations. We have connections to public and private hospitals in case of emergencies. All psychotherapists are also trained and have experience working with clients with severe mental health disorders and trained in this manual. Prof. Eva Heim, UniL Supervisor has connections with therapy developers in case any changes or accommodations to treatment is needed. This way we have local and international support of experts to ensure that we provide the best care for participants.

Other ethical considerations include the voluntary nature of participation in the project. Given the strain on public services in Egypt, the difficulty in accessing care, and the need for out-of-pocket payments, participation in our study may be the only affordable option for certain participants to receive

appropriate psychotherapeutic care. This may act as a strength in offering an additional option for care, but it may also be an ethical consideration. Our study offers them a standardized intervention that is based on and supported by evidence as an effective treatment for CPTSD, which is a better option than existing care options.

Finally, due to constraints in budget and time, not all participants will be able to complete all four modules. Instead, some participants will only receive three modules. This raises an ethical concern regarding the need to ensure equal benefits for all participants. In module 4 of narrative exposure therapy, the focus is primarily on addressing symptoms of PTSD. The other three modules, on the other hand, are designed to target the symptom clusters associated with CPTSD and have been the main focus of cultural adaptation efforts. Thus, to the best of our ability and within the limitations at hand, every participant—including those who were not selected for module 4—receives a thorough intervention designed to improve functioning, reduce symptoms of CPTSD, and promote general well-being.

4.1. Risk- benefit assessment and management

Our study's main benefit is that it may reduce psychological distress and improve functioning. ESTAIR is an evidence-based intervention. Our cultural adaptations have relied on evidence-based literature and fieldwork. Based on these facts, we assume that the ESTAIR intervention can reduce psychological distress symptoms.

The study entails only minimal risks for participants. The ESTAIR manual corresponds to the guidelines for treating PTSD. Yet, there is a risk that parts of the intervention will destabilize the participants during therapy. Evidence from face-to-face treatments suggests that between 5% and 10% of all patients experience a deterioration of their symptoms during treatment. However, this destabilization will be temporary, and overall, on the longer term, the program is considered beneficial, as evidence shows that culturally adapted trauma-focused interventions are effective [49] . Furthermore, the manual's first module, emotion regulation skills, aims to teach participants how to manage difficult emotions and stress. This will help them during the course of the intervention.

As in any clinical study, severe adverse events such as misuse of alcohol or drugs, self-harm, or suicidal ideation or attempts can occur during participation in the trial. The therapists will receive regular supervision from senior experts. They are trained for situations of crisis, such as severe emotional distress, dissociation, a temporal increase of suicidal thoughts, or other negative reactions to the treatment. Please refer to Section 4.2 for the protocol for adverse events and crisis situations.

Participants will receive therapy at no cost and will be compensated for all assessment and feedback interviews. Aside from attending the therapeutic program and assessments, no other commitments will be asked from them.

4.2. Adverse Events

Procedures to handle Adverse Event AE

An Adverse Event (AE) is any untoward medical occurrence in a patient or a clinical investigation subject that does not necessarily have a causal relationship with the trial procedure. An AE can therefore be any unfavorable or unintended finding, symptom, or disease temporarily associated with a trial procedure, whether or not related to it.

A Serious Adverse Event (SAE) is any untoward medical occurrence that results in death, is life-threatening, or requires in-patient hospitalization or prolongation of existing hospitalization.

Although likely uncommon, all adverse events (AEs) and serious adverse events (SAEs) reported by the participant or identified by the therapists at any time will be recorded for immediate action and resolution where required to ensure participant safety.

All SAEs are documented and reported immediately (within a maximum of 24 hours) to the UniL Supervisor, Prof. Eva Heim, and the AUC Advisor, Dr. Kate Ellis. The team will have a debriefing meeting, and the concerned ethics committees will be informed, within 15 days.

As a part of the study procedures, all participants who will be included in the study will receive a list of available mental health services. Please see Appendix 6. These services include emergency services and other out-patient services, if necessary. Out-patient clinics are provided if participants require psychiatric medication consultations during the study. All services are trusted and offer standard care. During the introductory session, therapists will remind participants of this and direct them to emergency services. They will also inform participants that if they notice any changes in suicidal thoughts or psychotic symptoms, they should report them. Intermediate assessments will include an oral check for suicidality. We will provide participants with the therapists' work phone number, emphasizing that they should only use it in emergencies. They will also be informed that, due to work schedules, therapists may take up to 24 hours to respond to their calls. Should a therapist receive a phone call from participant they will assess the risk:

If the risk is not imminent, the therapist will provide information on where to seek care and remind participants of key emotion regulation techniques to tolerate distress until the next group meeting. See the services list for referral information, which comprises a list of mental health services including psychiatric, psychological, and alternative sources of help (e.g., specialized phone hotlines).

If the risk is imminent, the therapist will suggest the following: If possible, the participant should find someone trusted to stay with them or, in cases of emergencies, accompany them immediately to their respective services. If the participant cannot contact a trusted person, the therapist can ask him or her to provide their phone number. The therapist can then contact the trusted person and describe the situation. The therapist will call the participant again after calling the trusted person to update them. If no trusted person is available, the therapist will direct participants to seek emergency services on their own or contact relevant hotlines, such as suicide hotlines. The therapist will call again to check on the participant.

Therapists are trained to handle such situations, and all similar situations will be brought to group or peer supervision meetings.

In the case when one of the therapeutic teams wants to discuss or receive feedback from the rest of the team regarding the state of a specific client, such information will be discussed in team supervision and peer supervision meetings, which include both psychologists and psychiatrists for multi-disciplinary clinical perspectives. The confidentiality of patients will be respected. In the case of pre-mature termination due to risk or AE, the UniL Supervisor, Prof. Eva Heim, and the AUC Advisor, Dr. Kate Ellis, will be informed.

4.3. Guidelines and regulations

Study procedures will respect the Declaration of Helsinki, international laws such as the Medical Research Involving Human Subjects Act (WMO), the Swiss Human Research Act (HRA) and the Human Research Ordinance (HRO), as well as other locally relevant legal and regulatory requirements in Egypt.

4.4. Amendments

Substantial changes to the project set-up, the protocol, and relevant project documents will be submitted to the Ethics Committee for approval before implementation.

In cases of emergency, changes to the protocol that preserve the rights, safety, and welfare of participants may be carried out without Ethics Committee authorization. Any deviations of this kind will be recorded and promptly reported to the Ethics Committee.

5. Data management and protection

5.1. Data recording

All necessary measures will be taken to encrypt all personal data in such a way that it will not be possible to attribute data to specific persons. Participants will be coded with randomly generated participant IDs. Quantitative data (i.e., sociodemographic information and clinical questionnaires) will be collected in paper/pencil format and recorded in an electronic Case Report Form (eCRF) in REDcap, (Research Electronic Data Capture), a web-based software platform designed to capture research data. They will be entered into the database (REDCap®) by the applicant and research assistant.

Qualitative interviews will be recorded and transcribed verbatim. In-person interviews and focus group discussions will be audio-recorded over MP3 or WAV audio files. Audio recordings will be collected using a device that is not connected to the internet. Zoom interviews will be automatically recorded via Zoom application on the UniL protected computer of the applicant. All audio interviews will be stored on the Tresorit secure storage service offered by UniL for transcription. Interviews will be transcribed by research assistants who are subject to the same confidentiality rules as the project authorized personnel. Please refer to the data management plan in Appendix 9.

5.2. Confidentiality and retention

Project data will be handled with uttermost discretion and is only accessible to authorized personnel using solely encrypted laptops. All research records will be kept confidential, and access will be limited to the applicant and primary research team members. Participants in study documents will be solely identified by their corresponding participant number. Using REDcap® will allow us to have an audit trail of quantitative data, enabling easy tracking and monitoring. After entering quantitative data into REDCap all documents will first be stored in a secure office in AUC, and then transferred according to our data protection agreement to be stored in UniL. Access to offices will be restricted to authorized persons. Consent forms will be scanned and saved on Tresorit before transferred to UniL. Please refer to the DMP and the Data protection agreement in Appendices 9 and 10.

Qualitative data will be stored using Tresorit, offered by UniL, a file storage and sharing service. It is a specific service for sensitive data: it offers enhanced security through advanced access control and data encryption. The data will be encrypted by Tresorit, and encryption keys are accessible only to the authorized personnel via a double authentication process. Audio recordings will be deleted upon completion of the transcripts. The transcripts will be pseudonymized by adding an identifier/code and removing any information that could identify the participant (e.g., names, email, phone number, job titles, or places of work). The code list will be stored physically, separated from the data, and destroyed upon completion of the project. Final transcripts will be uploaded and archived on the encrypted Tresorit server (backed up), and the code list will be physically separated from the data and destroyed upon completion of the project. For each transcript, an immutable

initial backup will be made, and all access to the encryption keys used to read and write the secured data will be automatically recorded and logged by Tresorit. The stored data will be backed up on a regular basis.

The encrypted study data are stored in an archive for a period of 10 years following the conclusion of the study or if the study is terminated prematurely. Following completion of the study in Egypt, the code list will be destroyed, hence data stored in UniL archives will be anonymized. Informed consent forms will be stored in the physical archives of the Institute of Psychology at University of Lausanne for 10 years. Please see the data management plan for exact details in Appendix 9.

5.3. Data protection agreement UniL/AUC

An official data protection agreement has been drafted and agreed upon by UniL and AUC; clearly identifying the roles and rights of both institution of this collaboration regarding data access, transfer, and protection. The agreement is currently has been signed and ratified by both parties. Intellectual property of data generated will be owned by University of Lausanne. Should there be any use of additional online and archival sources, aside from collected data, sources will be cited and clearly acknowledged in research outputs. The full agreement can be found in Appendix 10.

6. Pilot registration

This uncontrolled pilot study will be registered under clinicaltrials.gov.

7. Results management / Publications

Results of this pilot project will be published in the forms peer-reviewed papers and presented at scientific conferences by the research team. Papers will be included in the PhD dissertation of the applicant (NH) as chapters. Participants are informed of this in their consent forms and will be reminded of it in their final debriefing interview, where they will be invited to contact the researchers should they be interested in receiving a brief with study summary.

8. Funding

The project is financed by the Olivier Cadot Prize 2023 offered by the Christophe Pralong association and UniL. The PI's research stay in Egypt is funded by the Mobility Doc. grant by UniL.

9. Declaration of interest

All participating researchers declare that they have no competing interests.

10. Time plan overview

Task	Months					
	3-6	7-10	11-2	3-6	7-10	11-2
Phase 2: Formative research & analysis	■					
Phase 3: Adaptation & pilot						
Adaptations of diagnostic manual			■			
Pre- Assessment + Module 1,2					■	
Module 3,4 + post-assessment						■
Ongoing analysis of findings					■	

Notes: Time plan duration: March 2023-February 2025.

Group therapy sessions will start in week of 18th of August and end by week of 22nd December. This is a tentative schedule and may subject to change by one or two weeks based on progression of study.

11. Expected outcomes & relevance

The project will be the first to provide comprehensive investigation of cultural and structural aspects related to CPTSD in Egypt. It will contribute to exploring cultural variation in CPTSD and developing the first diagnostic cultural module for people from the MENA region. Furthermore, the cultural adaption of the ESTAIR manual will be the first to establish a disorder-specific therapeutic manual for CPTSD in the region. After assessing the feasibility and acceptability of this study, we aim to test the efficacy of this therapeutic manual and validate this diagnostic cultural module in a fully powered randomized controlled trial (RCT), for which we will seek separate funding and ethical approvals.

Egypt has very limited mental health resources [60]. The project insights will contribute to a sensibilization towards cultural and structural aspects, and their relevance for psychopathology and treatment in Egypt. Through this manual the scope of the project may expand to include further collaborations in Egypt with local and international NGOs working with refugees and vulnerable groups from the general population (e.g., Red Cross, Caritas, Médecins sans Frontier). We also aim to utilize existing connections to the General Secretariat of Mental Health, and Teaching Hospitals (e.g., Cairo and Alexandria University) to scale up and disseminate the intervention or train MHPs to use the 25-session manual in efforts to address the treatment gap.

The issue of structural aspects in psychopathology has been neglected so far. Studying structural factors is of particular importance to treatment efficacy in countries like Egypt where there is elevated risk of traumatic exposure. The implications of this project go beyond the direct target population. Egypt provides a solid example of the effects of severe and long-term forms of traumatic experiences in the MENA region. Hence, given cultural similarities, the project will also provide insights for similar studies set in the region or for refugees who originate from the MENA.

12. References

1. WHO, *International classification of diseases for mortality and morbidity statistics (11th Revision)*. 2018: World Health Organization. .
2. Brewin, C.R., et al., *A review of current evidence regarding the ICD-11 proposals for diagnosing PTSD and complex PTSD*. Clin Psychol Rev, 2017. **58**: p. 1-15.
3. Weiss, M.G., et al., *Culture and Social Structure in Comprehensive Case Formulation*. The Journal of nervous and mental disease, 2021. **209**(7): p. 465-466.
4. Brewin, C.R., *Complex post-traumatic stress disorder: A new diagnosis in ICD-11*. BJPsych Advances, 2020. **26**(3): p. 145-152.
5. Maercker, A., et al., *Diagnosis and classification of disorders specifically associated with stress: Proposals for ICD-11*. World Psychiatry, 2013. **12**(3): p. 198-206.
6. Brewin, C.R., et al., *A review of current evidence regarding the ICD-11 proposals for diagnosing PTSD and complex PTSD*. Clinical Psychology Review, 2017. **58**: p. 1-15.
7. Ho, G.W.K., et al., *The validity of ICD-11 PTSD and Complex PTSD in East Asian cultures: Findings with young adults from China, Hong Kong, Japan, and Taiwan*. European Journal of Psychotraumatology, 2020. **11**(1): p. 1717826.
8. Hyland, P., et al., *Are posttraumatic stress disorder (PTSD) and complex-PTSD distinguishable within a treatment-seeking sample of Syrian refugees living in Lebanon?* Global Mental Health, 2018. **5**.
9. Knefel, M., et al., *The replicability of ICD-11 complex post-traumatic stress disorder symptom networks in adults*. The British Journal of Psychiatry, 2019. **214**(6): p. 361-368.
10. Knefel, M., et al., *A Cross-Cultural Comparison of ICD-11 Complex Posttraumatic Stress Disorder Symptom Networks in Austria, the United Kingdom, and Lithuania*. Journal of Traumatic Stress, 2020. **33**(1): p. 41-51.
11. Nickerson, A., et al., *The factor structure of complex posttraumatic stress disorder in traumatized refugees*. European Journal of Psychotraumatology, 2016. **7**: p. 33253-33253.
12. Owczarek, M., et al., *Testing the factor structure of the International Trauma Questionnaire (ITQ) in African community samples from Kenya, Ghana, and Nigeria*. Journal of Loss and Trauma, 2020. **25**(4): p. 348-363.
13. Redican, E., et al., *A systematic literature review of factor analytic and mixture models of ICD-11 PTSD and CPTSD using the International Trauma Questionnaire*. Journal of Anxiety Disorders, 2021. **79**: p. 102381.
14. Roberts, N.P., et al., *International Trauma Interview (ITI) for ICD-11 PTSD and complex PTSD (Test Version 3.1)*. 2018.
15. Gureje, O., et al., *Systematic inclusion of culture-related information in ICD-11*. World Psychiatry, 2019. **18**(3): p. 357-358.
16. Maercker, A., et al., *Proposals for mental disorders specifically associated with stress in the International Classification of Diseases-11*. Lancet, 2013. **381**(9878): p. 1683-5.
17. Herman, J.L., *Complex PTSD: A syndrome in survivors of prolonged and repeated trauma*. Journal of Traumatic Stress, 1992. **5**(3): p. 377-391.
18. American Psychiatric Association, *Diagnostic and statistical manual of mental disorders: DSM-IV. (4th ed.)*. 1994, Washington, DC: American Psychiatric Association.

19. Pelcovitz, D., et al., *Development of a criteria set and a structured interview for disorders of extreme stress (SIDES)*. Journal of Traumatic Stress, 1997. **10**(1): p. 3-16.
20. de Jong, J.T., et al., *DESNOS in three postconflict settings: Assessing cross-cultural construct equivalence*. Journal of Traumatic Stress, 2005. **18**(1): p. 13-21.
21. Heim, E., T. Karatzias, and A. Maercker, *Cultural concepts of distress and complex PTSD: Future directions for research and treatment*. Clinical Psychology Review, 2022. **93**: p. 102143.
22. Lewis-Fernández, R. and L.J. Kirmayer, *Cultural concepts of distress and psychiatric disorders: Understanding symptom experience and expression in context*. Transcultural Psychiatry, 2019. **56**(4): p. 786-803.
23. Kwon, H., et al., *Cultural and gender differences in emotion regulation: Relation to depression*. Cognition and Emotion, 2013. **27**(5): p. 769-782.
24. Nagulendran, A. and L. Jobson, *Exploring cultural differences in the use of emotion regulation strategies in posttraumatic stress disorder*. European Journal of Psychotraumatology, 2020. **11**(1): p. 1729033.
25. Engelbrecht, A. and L. Jobson, *Self-concept, post-traumatic self-appraisals and post-traumatic psychological adjustment: what are the relationships?* Behavioural and Cognitive Psychotherapy, 2020. **48**(4): p. 463-480.
26. Fessler, D., *Shame in Two Cultures: Implications for Evolutionary Approaches*. Journal of Cognition and Culture, 2004. **4**(2): p. 207-262.
27. Campos, B. and H.S. Kim, *Incorporating the cultural diversity of family and close relationships into the study of health*. American Psychologist, 2017. **72**(6): p. 543-554.
28. Hansford, M. and L. Jobson. *Social support and self-construal as moderators of lifetime trauma exposure on posttraumatic stress disorder symptoms*. Educational Publishing Foundation [doi:10.1037/trm0000281]. 2021.
29. Hosny, N., et al., *How is post-traumatic and complex posttraumatic stress disorder experienced and expressed in populations from the Middle East and North Africa? (Manuscript submitted for publication)*. 2023.
30. Bovey, M., et al., *A systematic review of qualitative research on PTSD and Complex-PTSD in Sub-Saharan Africa (Manuscript in preparation)*. 2022.
31. Killikelly, C., M. Ramp, and A. Maercker, *Prolonged grief disorder in refugees from Syria: qualitative analysis of culturally relevant symptoms and implications for ICD-11*. Mental Health, Religion & Culture, 2021. **24**(1): p. 62-79.
32. Killikelly, C., et al., *Development of the international prolonged grief disorder scale for the ICD-11: Measurement of core symptoms and culture items adapted for Chinese and German-speaking samples*. Journal of Affective Disorders, 2020. **277**: p. 568-576.
33. Hinton, D.E., et al., *Culturally sensitive assessment of anxious-depressive distress in Vietnam: Avoiding category truncation*. Transcultural Psychiatry, 2018. **55**(3): p. 384-404.
34. Hinton, D.E., et al., *Culturally sensitive assessment of anxious-depressive distress in the Cambodian population: Avoiding category truncation*. Transcultural Psychiatry, 2019. **56**(4): p. 643-666.
35. Lewis-Fernández, R., et al., *Culture and psychiatric evaluation: Operationalizing cultural formulation for DSM-5*. Psychiatry, 2014. **77**(2): p. 130-154.
36. Paralikar, V.P., A. Deshmukh, and M.G. Weiss, *Qualitative analysis of cultural formulation interview: findings and implications for revising the outline for cultural formulation*. Transcultural Psychiatry, 2019. **57**(4): p. 525-541.

37. Holmes, S.M., et al., *Misdiagnosis, mistreatment, and harm - When medical care ignores social forces*. N Engl J Med, 2020. **382**(12): p. 1083-1086.
38. Boxer, P., et al., *Exposure to Violence Across the Social Ecosystem and the Development of Aggression: A Test of Ecological Theory in the Israeli–Palestinian Conflict*. Child Development, 2013. **84**(1): p. 163-177.
39. Hinton, D.E., et al., *Adapting CBT for traumatized refugees and ethnic minority patients: Examples from culturally adapted CBT (CA-CBT)*. Transcultural Psychiatry, 2012. **49**(2): p. 340-65.
40. Koch, T., T. Ehring, and A. Liedl, *Effectiveness of a transdiagnostic group intervention to enhance emotion regulation in young Afghan refugees: A pilot randomized controlled study*. Behaviour Research and Therapy, 2020. **132**: p. 103689.
41. Karatzias, T. and M. Cloitre, *Treating adults with complex posttraumatic stress disorder using a modular approach to treatment: Rationale, evidence, and directions for future research*. Journal of Traumatic Stress, 2019. **32**(6): p. 870-876.
42. Bohus, M., et al., *Dialectical Behavior Therapy for Posttraumatic Stress Disorder (DBT-PTSD) Compared With Cognitive Processing Therapy (CPT) in Complex Presentations of PTSD in Women Survivors of Childhood Abuse: A Randomized Clinical Trial*. JAMA Psychiatry, 2020. **77**(12): p. 1235-1245.
43. Karatzias, T., et al., *Psychological interventions for ICD-11 complex PTSD symptoms: Systematic review and meta-analysis*. Psychological Medicine, 2019. **49**(11): p. 1761-1775.
44. Murray, L.K., et al., *A Common Elements Treatment Approach for adult mental health problems in low- and middle-income countries*. Cognitive and Behavioral Practice, 2014. **21**(2): p. 111-123.
45. Cloitre, M. and J.A. Schmidt, *STAIR Narrative Therapy*, in *Evidence based treatments for trauma-related psychological disorders*, U. Schnyder and M. Cloitre, Editors. 2015, Springer International Publishing. p. 277–297.
46. Cloitre, M., et al., *Treatment for PTSD related to childhood abuse: A randomized controlled trial*. American Journal of Psychiatry, 2010. **167**(8): p. 915-24.
47. Arundell, L.L., et al., *The effectiveness of adapted psychological interventions for people from ethnic minority groups: A systematic review and conceptual typology*. Clin Psychol Rev, 2021. **88**: p. 102063.
48. Hall, G.C.N., et al., *A meta-analysis of cultural adaptations of psychological interventions*. Behavior Therapy, 2016. **47**(6): p. 993-1014.
49. Ennis, N., et al., *Treating posttraumatic stress disorder across cultures: A systematic review of cultural adaptations of trauma-focused cognitive behavioral therapies*. Journal of Clinical Psychology, 2020. **76**(4): p. 587-611.
50. Bank, W., *Poverty & Equity Brief, Arab Republic of Egypt 2021*, World Bank
51. Nosier, S., R. Beram, and M. Mahrous, *Household Poverty in Egypt: Poverty Profile, Econometric Modeling and Policy Simulations*. 2021, SIMAR, Bibliotheca Alexandrina: Alexandria, Egypt.
52. El-Zanaty, F. and A. Way, *Egypt Demographic and Health Survey*. 2015: Cairo, Egypt.
53. Gilbert, R., et al., *Child maltreatment: Variation in trends and policies in six developed countries*. The Lancet, 2012. **379**(9817): p. 758-772.
54. Schaer, C., *Economic crisis: Is Egypt the 'new Lebanon?'*. 2023, Deutsche Welle Deutsche Welle
55. Tadros, M., *Politically Motivated Sexual Assault and the Law in Violent Transitions: A Case Study from Egypt*, in *Sexuality, Poverty and Law*. 2013, Institute of Development Studies Brighton. p. 32.

56. ATAS, A.I.f.T.a.a.-v.s., *Andalus Institute report on the thermometer violence in Egypt and the increasing severity in different events*. 2016.
57. Ribeiro, W.S., et al., *The Impact of Epidemic Violence on the Prevalence of Psychiatric Disorders in Sao Paulo and Rio de Janeiro, Brazil*. PLOS ONE, 2013. **8**(5): p. e63545.
58. Green, G., et al., *A scoping review of how exposure to urban violence impacts youth access to sexual, reproductive and trauma health care in LMICs*. Global Public Health, 2022: p. 1-18.
59. Drew, N., et al., *Human rights violations of people with mental and psychosocial disabilities: An unresolved global crisis*. The Lancet, 2011. **378**(9803): p. 1664-1675.
60. Elnemais Fawzy, M., *Mental health care in Egypt: Review of current state, policy, and needs*. International Journal of Mental Health, 2017. **46**(4): p. 339-345.
61. Böttche, M., et al., *From formative research to adaptation of an evidence-based cognitive-behavioural intervention: Decision-making processes for face-to-face and internet-based cultural adaptation for Arabic-speaking refugees in Germany*. Clinical Psychology in Europe, 2021. **3**(Special Issue): p. Article e4623.
62. Kananian, S., et al., *Culturally adapted cognitive behavioral therapy plus problem management (CA-CBT+) with Afghan refugees: A randomized controlled pilot study*. Journal of Traumatic Stress, 2020. **33**(6): p. 928-938.
63. Lotzin, A., et al., *STARC-SUD – Adaptation of a transdiagnostic intervention for refugees with substance use disorders*. Clinical Psychology in Europe, 2021. **3**(Special Issue): p. Article e5329.
64. Shala, M., et al., *Cultural adaptation of Hap-pas-Hapi, an internet and mobile-based intervention for the treatment of psychological distress among Albanian migrants in Switzerland and Germany*. Internet Interventions, 2020. **21**: p. 100339.
65. Boxer, P., et al., *Exposure to violence across the social ecosystem and the development of aggression: A test of ecological theory in the Israeli–Palestinian conflict*. Child Development, 2013. **84**(1): p. 163-177.
66. Miller, K.E. and A. Rasmussen, *War exposure, daily stressors, and mental health in conflict and post-conflict settings: bridging the divide between trauma-focused and psychosocial frameworks*. Social science & medicine, 2010. **70**(1): p. 7-16.
67. de Ribera, O.S., et al., *Correlates of youth violence in low- and middle-income countries: A meta-analysis*. Aggression and Violent Behavior, 2019. **49**: p. 101306.
68. Kamel, M.M., et al., *Mental health outcomes and help-seeking behaviours among Egyptian medical students: A cross-sectional study*. Early Intervention in Psychiatry, 2022. **16**(9): p. 1020-1027.
69. Robinson, O.C., *Sampling in Interview-Based Qualitative Research: A Theoretical and Practical Guide*. Qualitative Research in Psychology, 2014. **11**(1): p. 25-41.
70. Silverman, D., *Doing Qualitative Research*. 2021, SAGE Publications Ltd: London.
71. Ibrahim, H., et al., *The validity of Posttraumatic Stress Disorder Checklist for DSM-5 (PCL-5) as screening instrument with Kurdish and Arab displaced populations living in the Kurdistan region of Iraq*. BMC Psychiatry, 2018. **18**(1): p. 259.
72. Miller-Graff, L., K. Ellis, and N. Hosny, *PTSD Coach Online-Arabic: A Randomized Controlled Pilot Trial to Examine Feasibility, Acceptability, and Preliminary Effectiveness*. J Trauma Stress, 2021. **34**(1): p. 23-34.
73. Kroenke, K., R.L. Spitzer, and J.B. Williams, *The PHQ-9: validity of a brief depression severity measure*. J Gen Intern Med, 2001. **16**(9): p. 606-13.
74. Gierk, B., et al., *The somatic symptom scale-8 (SSS-8): a brief measure of somatic symptom burden*. JAMA Intern Med, 2014. **174**(3): p. 399-407.

75. Gierk, B., et al., *The somatic symptom scale-8 (SSS-8): a brief measure of somatic symptom burden*. JAMA Internal Medicine, 2014. **174**(3): p. 399-407.
76. Bech, P., et al., *Measuring well-being rather than the absence of distress symptoms: a comparison of the SF-36 Mental Health subscale and the WHO-Five well-being scale*. International Journal of Methods in Psychiatric Research, 2003. **12**(2): p. 85-91.
77. Cloitre, M., et al., *Treatment for PTSD Related to Childhood Abuse: A Randomized Controlled Trial*. American Journal of Psychiatry, 2010. **167**(8): p. 915-924.
78. R_Core_Team, *R: A Language and Environment for Statistical Computing*. 2023, R Foundation for Statistical Computing: Vienna, Austria.
79. Gale, N.K., et al., *Using the framework method for the analysis of qualitative data in multi-disciplinary health research*. BMC Medical Research Methodology, 2013. **13**(1): p. 117.
80. VERBISoftware, *MAXQDA 2024 [computer software]*. 2024: Berlin, Germany.