Randomized Clinical Trial to evaluate efficacy, feasibility and appropriateness of MEmory Training for Recovery- Adolescent (METRA) among adolescents: A structured summary of a study protocol for a randomized controlled trial

**Abstract**

**Background**: Adolescent youth in low- and middle-income countries (LMICs) generally do not receive evidence-based psychological interventions, as most interventions are complex, require specialist knowledge, and are prohibitively expensive. This study aims to investigate the efficacy of MEmory Training for Recovery-Adolescent (METRA) in improving psychological symptoms (posttraumatic stress disorder, depression) in adolescents. Our secondary aims are to examine the feasibility and appropriateness of METRA, explore the mechanisms mediating treatment effects, and include a cost-analysis of METRA in LMIC humanitarian contexts.

**Methods**: We will use mixed methods to assess feasibility, appropriateness, and efficacy. The project will also include an embedded mechanism study and cost analysis component.

**Discussion**: Research outputs include an evaluation of METRA, an innovative, low-intensity, freely-available intervention that can be delivered by individuals with minimal training in humanitarian contexts. We anticipate that refugee and war-affected adolescents in LMICs who experience high levels of psychological distress will benefit from this research.

**Trial registration**: The trial is preregistered with ANZTCR (Trial ID: ACTRN12622001413718).

**Keywords**

Adolescent; Refugee; War-affected; Memory Training for Recovery; Trauma; Depression

**Introduction**

**Background and rationale {6a}**

Trauma-exposed adolescents in low- and middle-income countries (LMICs) can experience concerning levels of psychological distress, including posttraumatic stress disorder (PTSD), depression, and anxiety (Attanayake, McKay, Joffres, Singh, Burkle, & Mills, 2009; Blackmore et al., 2020; Morina, von Lersner, & Prigerson, 2011; Tyrer & Fazel, 2014). These symptoms severely affect an adolescent’s life, including long-lasting cognitive, emotional, social and academic/vocational problems (Neshat-Doost, Yule, Kalantari, Rezvani, Dyregrov, & Jobson, 2013). Addressing psychological concerns in the critical developmental period of adolescence is imperative (Neshat-Doost et al., 2013; The Economist, 2019). However, very adolescents in LMICs receive evidence-based interventions, due to high costs, limited mental health services and a shortage of skilled professionals (Juengsiragulwit, 2015; Zia, Afkhami, Tavakoli, Neshat-Doost, & Jobson, in press; Kohrt et al., 2018). The needs of adolescents in LMICs have not received sufficient attention in psychology and psychiatry research (Frontiers in Psychiatry, 2019). In order to meet these identified needs, we propose that MEmory Training for Recovery-Adolescent (METRA), a low-intensity, accessible and scalable evidence-based intervention, will improve adolescent mental health (specifically depression and PTSD), .

**Trauma and Memory**

Those suffering from depression and PTSD, including adolescent refugees and war-affected youth (Neshat-Doost et al., 2013), exhibit certain disruptions in their autobiographical remembering (i.e., remembering personal experiences from one’s life) (Brewin, 2011; Dalgleish & Werner-Seidler, 2014). Trauma memories are often intrusive and distressing (Brewin, 2011) and PTSD sufferers have considerable difficulties remembering specific events from their lives (e.g., “I attended Adina’s party on Friday”). Instead, they provide overgeneral memories (OGM) of events (“I was attending a party every weekend”) (Williams et al., 2007). OGM develops as a cognitive avoidance strategy in response to the distressing memories one may experience (Williams et al., 2007).

OGM is problematic as it is associated with impaired social problem-solving, cognitive avoidance, rumination, impairments in executive control, difficulty imagining specific events in the future (Kleim, Graham, Fihosy, Stott, & Ehlers, 2014; Sutherland & Bryant, 2008; Williams et al., 2007), and difficulty accessing specific information about the past, which interferes with the ability to update distressing memories (Moradi, Moshirpanahi, Parhon, Mirzaei, Dalgleish, & Jobson, 2014; Williams et al., 2007). Each of these processes are integral to recovery from PTSD and depression (Moradi et al., 2014; Neshat-Doost et al., 2013). Not surprisingly, an OGM retrieval style in adolescents has been found to predict on-going psychological difficulties, which can persist well into adulthood affecting social functioning and academic/vocational attainment (Hitchcock, Nixon, & Weber, 2014).

There is enormous untapped potential to improve the psychological functioning of trauma-exposed adolescents by targeting these memory difficulties that underpin posttraumatic psychological distress. In response to this, we propose that MEmory Training for Recovery-Adolescents (METRA), a novel intervention for use in LMIC and humanitarian contexts (Moradi et al., 2014; Neshat-Doost et al., 2013), may have potential in improving the psychological adjustment of adolescents.

**Feasibility and Piloting of METRA Modules**

METRA is an evidence-based, low-intensity, easily disseminable, transdiagnostic training package. It is comprised of two modules that target major cognitive features underpinning posttrauma psychological difficulties experienced by adolescent refugees; OGM and trauma/distressing memories.

Module 1 is a memory specificity training that teaches adolescents to recall specific positive, negative and neutral everyday memories from their lives (targets OGM) (Raes, Williams, & Hermans, 2009). Module 2 is a writing for recovery, written exposure training (e.g., Kalantari, Yule, Dyregrov, Neshat-Doost, & Ahmadi, 2012; Sloan et al., 2018; Sloan & Marx, 2019) targeting distressing and trauma memories. Adolescents are supported in writing about their past including thoughts and feelings. The results of our pilot research, investigating the efficacy of the components of METRA, have been promising in the treatment of depression and PTSD in refugee adolescents and war veterans in LMICs (see Ahmadi, Kajbaf, Neshat Doost, Dalgleish, Jobson, & Mosavi, 2018; Kalantari et al., 2012; Moradi et al., 2014; Neshat-Doost et al., 2013). Furthermore, our studies have shown preliminary support that these modules were feasible in humanitarian settings, the training was well received by participants and organizations, and adolescents reported satisfaction and were motivated (Ahmadi et al., 2018; Kalantari et al., 2012; Moradi et al., 2014; Neshat-Doost et al., 2013).

METRA aligns with humanitarian initiatives aiming to deliver more accessible, low-resource (i.e., group-based, unskilled facilitator) psychosocial evidence-based interventions (Elrha, 2015). METRA, a low-intensity intervention, seems feasible in humanitarian settings and has potential for reducing PTSD and depression symptoms in adolescents. There is a need to better understand the mechanisms driving the therapeutic effects of METRA and the costs associated with implementing METRA in humanitarian contexts. This project addresses identified humanitarian mental health research gaps (Elrha, 2015) by investigating the efficacy and feasibility of scaling-up a low-intensity modular transdiagnostic psychosocial interventions for adolescents. It also includes qualitative methods to examine appropriateness and acceptability of METRA and a cost-analysis of the intervention.

**Objectives**

Primary Objectives

1) Investigate the efficacy of METRA in improving psychological symptoms (posttraumatic stress disorder, depression) in adolescents.

Secondary Objectives

2) Investigate the feasibility and appropriateness of METRA for adolescents delivered in LMIC humanitarian contexts.

3) Examine the mechanisms mediating treatment effects.

4) Include a cost-analysis of METRA in LMIC humanitarian contexts

**Trial design**

This is a randomised controlled trial (RCT) comparing METRA to treatment as usual (TAU) (Objective 1), with an embedded qualitative (Objective 2), and mechanism (Objective 3) and cost-analysis (Objective 4) study. Participants will be assessed; 1) at baseline, 2) at post-Module 1, 3) at post-Module 2, and 4) at 3-month follow-up. The first three assessments are face-to-face assessment and will include all measures. The follow-up assessments will be conducted by phone/skype/zoom and will include the primary and secondary outcomes. Assessments will be conducted by independent raters who have no therapeutic relationship with participants and are blind to condition.

**Methods: Participants, interventions and outcomes**

**Eligibility criteria**

Iraqi adolescents residing in Kirkuk aged 10-19 years with elevated psychological distress. This age range aligns with our pilot work and definitions of ‘adolescent’ (UNICEF, 2019b; WHO, 2019). As in our pilot studies, elevated psychological distress is defined as >25 on the Child Revised Impact of Event Scale-13 (Child Outcomes Research Consortium, 2019) and/or >12 on the Mood and Feeling Questionnaire – Short form (Neshat-Doost et al., 2006). Participants will be recruited in Kirkuk. We will aim to recruit 140 participants. Exclusion Criteria: a) high levels of suicidality, b) unmanaged psychosis/manic episodes in past month, and c) presence of head trauma/organic brain damage.

**Who will take informed consent?**

Researchers will gain informed consent from the adolescents and their guardians.

**Interventions**

Treatment as usual (TAU): Local NGOs will provide the course of intervention that they deem appropriate. No specific instructions will be given as to what TAU should entail, except not including elements specific to METRA. TAU will be documented ensuring understanding of the duration, frequency and type of treatment administered.

**Intervention description**
METRA: Module 1: Memory specificity training (Ahmadi et al., 2018; Moradi et al., 2014; Neshat-Doost et al., 2013; Raes et al., 2009; Martens et al., 2019) is a manualized training delivered over five 60-minute sessions to groups of 6-8 adolescents. MEST aims to enhance memory specificity through practice. Session 1 provides psycho-education about mental health and memory. Participants practice recalling memories in response to positive and neutral cues, with support from the group facilitator. Attention is paid to the contextual, spatio-temporal and sensory-perceptual details of the memories (Raes et al., 2009). Participants’ responses are discussed in the group. At the end of the session, homework exercises are introduced; for 10 cues (positive and neutral) participants need to generate a specific memory and are instructed to write down a ‘specific memory of the day’ (Raes et al., 2009). Session 2 starts with a brief summary of Session 1, the homework exercises are discussed and the Session then follows the same format as Session 1, with further practice focusing on recalling memories in response to positive and neutral cues. At the end of Session 2, the homework is explained; participants need to generate two different specific memories for 10 cues (positive and neutral) and write down two different ‘specific memories of the day’ (Raes et al., 2009). Session 3 is very similar to Session 2. However, in Session 3, participants also need to work with negative cues. The homework exercises are similar to those outlined in Session 2, but now also include negative cues. Session 4 involves further exercises using negative and (‘counterpart’) positive cues. It is also explained how overgeneral thinking can be addressed by recalling a single specific experience and examples are discussed to promote metacognitive awareness of when participants are starting to shift to unspecific thinking or more general retrieval (Raes et al., 2009). Session 5 includes further practice and a summary of Module 1. Module 1 focuses on everyday remembering.

Module 2: Writing for Recovery is a written exposure training involves five sessions (Kalantari et al., 2012; Sloan et al., 2018). In the first session the purpose of Module 2 is outlined. In the following sessions, the facilitator simply reads the instructions and the participant completes the writing task; writing about their trauma including thoughts and feelings. After 30 minutes, the facilitator instructs the participants to stop writing.

**Criteria for discontinuing or modifying allocated interventions**

Discontinue trial if participants report significant distress or a significant proportion of participants report significant increase in symptomatology. This will be based on the reports and observations of the facilitators and decisions to continue/discontinue will be made by the trial monitoring body.

**Strategies to improve adherence to interventions**

Group facilitators will be trained and receive supervision. A random 25% of the audio-recorded treatment sessions will be rated for manual adherence. To reduce group contamination, participants will be requested to not discuss treatment with others.

**Provisions for post-trial care**

Referrals to local mental health services and NGOs will be made for participants requiring further psychological care.

**Outcomes**

*Primary Outcomes*: self-reported symptoms of PTSD (Child Outcomes Research Consortium, 2019) and depression (Neshat-Doost et al., 2006). We will assess statistical and clinical significance (d>.20) of change in the levels of PTSD and depression symptoms in the intervention and control groups.

*Secondary Outcomes*: changes in quality of life (Edwards, Huebner, Connell, & Patrick, 2002); anxiety (Taghavi, & Alishahi, 2004); anxiety (Reynolds & Richmond, 1978); and internalising/externalising problems (Alavi et al., 2009).

*Process Measures*: rumination (Abela, Vanderbilt, & Rochon, 2004); and cognitive avoidance (Sexton & Dugas, 2008).

*Qualitative data*: Focus groups and key informant interviews will examine appropriateness and feasibility of METRA.

The measures and interviews will be conducted in Arabic

**Participant timeline**

Baseline Assessment

Randomization

METRA

Module1

TAU

Post-Module1 assessment

Assessment

METRA

 Module 2

TAU

Assessment

Post-METRA assessment

3-month follow-up assessment

3-month follow-up

Figure 1: Flowchart of participant recruitment and assessment

**Recruitment**

Participants will be recruited through local non-government agencies, community and schools in Kirkuk.

**Assignment of interventions: allocation**

Following baseline assessment, sequential participants will be randomized to METRA or TAU.

We will use consecutively numbered sealed opaque envelopes to conceal the allocation.

The research team will oversee generation of the allocation sequence, participant enrolment, and assigning participants to interventions.

**Assignment of interventions: Blinding**

**Who will be blinded**

Outcome assessors will be blind to hypotheses and group allocation. Group facilitators will be blind to hypotheses. Data analysts will be blinded to group allocation.

**Data collection and management**

**Plans for assessment and collection of outcomes**

Data will be collected at; 1) baseline, 2) post-Module 1, 3) post-Module 2, and 4) 3-month follow-up. Assessments will be conducted by independent raters who have no therapeutic relationship with participants and are blind to condition. All assessors will be trained and supervised in assessment procedures. All questionnaires have good reliability and validity and have been previously used cross-culturally.

**Plans to promote participant retention and complete follow-up**

Participants will be contacted using a variety of media, including phone, email and social media to promote retention and follow-up completion.

**Data management**

Data will be coded, entered and stored in Kirkuk on password protected computer systems. Anonymized data will be shared amongst the research team.

**Confidentiality**

Personal information about potential and enrolled participants will only be collected, shared, maintained and monitored by the research teams at each site. De-identified data will be shared between the team.

**Statistical methods**

**Statistical methods for primary and secondary outcomes**

All primary analyses will be on intent-to-treat principle, with all randomized participants analyzed in their allocation condition.

Objective 1: To assess the effect of intervention on outcomes, we will use a mixed linear model with intervention type, time, and intervention by time interaction as fixed factors. Repeated assessments of individuals will be modelled as random intercept. Of primary interest will be intervention by time interaction, which will compare the levels of change over time in outcomes of the intervention and control groups.

Objective 2: Thematic analysis of qualitative data (Atkins et al., 2017; Braun & Clark, 2006; Marks & Yardley, 2004) will assess feasibility and appropriateness.

Objective 3: Mediational analyses will be carried out using regression-based approach outlined by McKinnon et al. (2007). This will assess mechanisms of change (rumination, avoidance).

Objective 4: We will look at the difference in outcomes and costs between METRA and TAU, allowing us to explore the cost per point change in symptoms for both; we will also assess affordability of METRA by comparing the program cost with other mental health interventions in humanitarian contexts. Difference in outcomes will be assessed by examining point changes in PTSD and depression symptoms based on our outcome scales. For costs, we will do a bottom-up costing of both METRA and TAU whereby we identify all the inputs (e.g., staff time: X minutes at $X salary per minute, X rooms at $X per room, exclusive of research-related costs) and sum them. Then we can divide total cost by total point change for each intervention and compare them. Third, we will compare total and per patient METRA program cost with existing mental health budgets in humanitarian contexts to give an indication of whether implementing METRA is affordable in humanitarian settings.

**Methods for additional analyses (e.g. subgroup analyses)**

Exploratory Analyses: Potential moderators (age, gender, trauma exposure) of intervention response will be explored with linear mixed models.

**Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data**

Missing data will be kept as a separate category for each of the variables in the analysis.

**Oversight and monitoring**

**Composition of the coordinating centre and trial steering committee**

The research team will provide overall supervision of the project.

**Adverse event reporting and harms**

Should an adverse effect be reported, the Chief Investigators will be notified immediately and a plan to resolve the serious adverse effect will be formulated. Depending on the nature of the adverse event, the Chief Investigators and research team will determine the appropriate course of action and then the research team will discuss the situation fully with the participant. A complete list of adverse effects, the steps taken to resolve them, and the results of those steps, will be reported to the Ethics Review Committee monthly, while serious adverse effects will be reported within one business day.

**Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees)**

We will report changes to the ethic committees and trial registry.

**Dissemination plans**

The results will be published in peer-reviewed journal articles. There will also be an Engagement and Communication Strategy that will ensure key local (Iraqi) and international stakeholders are informed about the findings.

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 **Abbreviations**

PTSD: Posttraumatic stress disorder

METRA: MEmory Training for Recovery – Adolescents

**Declarations**

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**Availability of data and materials**

The research team will have the final dataset and this dataset will be available by contacting the researchers.
**Competing interests**

The principal investigators have no competing interests.

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