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What works for whom? Comparing Narrative Exposure Therapy and extended Problem Management Plus for trauma survivors in post-war Northern Uganda

Submission date
05/11/2025

Recruitment status
Recruiting

Registration date
06/11/2025

Overall study status
Ongoing

Last Edited
06/11/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Posttraumatic stress disorder (PTSD) is a common mental health problem in areas affected by conflict. PTSD can develop after frightening or painful experiences. People with PTSD may have strong memories or pictures of what happened, bad dreams, avoid reminders, or feel tense and alert. This study compares two types of treatment for people with PTSD: Narrative Exposure Therapy (NET): a treatment that helps people talk about and understand their past traumatic experiences. Extended Problem Management Plus (PM+): a treatment that helps people manage stress and daily challenges. The study aims to find out which treatment works better in reducing PTSD symptoms. It will also look at which personal and social factors affect how well a treatment works for a person.

Who can participate?
Adults between 18 and 65 years who have experienced traumatic events and have symptoms of PTSD.

What does the study involve?
Participants first take part in a diagnostic interview about their current life situation, past experiences, and mental health. Those who meet the study criteria are randomly assigned to one of the two interventions: NET or extended PM+. Each participant receives eight sessions of the assigned treatment. Follow-up interviews take place after three months and after twelve months to see how symptoms have changed.

What are the possible benefits and risks of participating?
By taking part, participants help improve knowledge about how to best support people with PTSD. Those who take part receive 10,000 UGX for each interview (at the start, after 3 months, and after 12 months) and reimbursement for transport costs. Strong emotions can arise during interviews or treatment. All mental health workers are trained to provide support if this happens.

Where is the study run from?
The study is run by Bielefeld University in Germany by Dr. Sarah Wilker in cooperation with Naser Morina (University Hospital Zurich, University of Zurich, Switzerland). The study takes place in Gulu, Uganda in cooperation with the vivo outpatient clinic for survivors of violence and torture.

When is the study starting and how long is it expected to run for?
November 2025 to July 2028

Who is funding the study?
The German Research Foundation and the Swiss National Science Foundation.

Who is the main contact?
1. Sarah Wilker, sarah.wilker@uni-bielefeld.de
2. Naser Morina, naser.morina@usz.ch
3. Anett Pfeiffer, anett.pfeiffer@vivo.org

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Sarah Wilker

ORCID ID
https://orcid.org/0000-0002-0887-4672

Contact details
Universitätsstraße 25
Bielefeld
Germany
33615
+49 (0)5211064491
sarah.wilker@uni-bielefeld.de

Type(s)
Scientific

Contact name
Dr Naser Morina

ORCID ID
https://orcid.org/0000-0002-6470-4408

Contact details
Rämistrasse 100
Zürich
Switzerland

8091
+41 (0)44 255 52 80
Naser.Morina@usz.ch

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
WI 5942/5-1

Study information

Scientific Title
One size fits all? Towards individual prediction of treatment success for posttraumatic stress disorder in post-conflict settings

Acronym
TRAUMA-FIT

Study objectives
Meta-analyses indicate average posttraumatic stress disorder (PTSD) prevalence rates of up to 23% in post-conflict regions (Charlson et al., 2019; Lim et al., 2022). This high need is opposed by a lack of mental health care and mental health research in low- and middle-income countries (LMICs). This necessitates further research into effective treatment options for PTSD in LMICs (Robson et al., 2019). In particular, research on the personalization of treatments in post-conflict settings is warranted, to allocate the limited mental health resources most effectively.

Against this background, TRAUMAFIT aims to:
1. Compare the effectiveness of Narrative Exposure Therapy (NET; Schauer, Neuner, & Elbert, 2011), a short and pragmatic trauma-focused treatment that was specially developed to meet the needs of survivors of war and torture (Nosè et al., 2017), and an extended version of Problem Management Plus (PM+, Dawson et al., 2015), a present-centered intervention developed to meet the diverse needs of conflict populations to cope with current adversity
2. Identify predictors of optimal response in the two conditions, and thereby identify predictors of treatment success in a trauma-focused versus present-focused treatment
3. Investigate the explanatory role of socio-ecological factors in PTSD treatment response

Given that NET is a more specific treatment for PTSD and based on previous evidence we hypothesize that NET will be superior to extended PM+ on average for the reduction of PTSD symptoms (Study A, Hypothesis 1). However, given considerable rates of non-response in trauma-focused interventions, we further hypothesize that it will be possible to develop an algorithm that differentiates individuals based on their optimal treatment, and that there will be a clinically meaningful difference in treatment response between individuals who received their optimal treatment compared to individuals who received their non-optimal treatment (Study B, Hypothesis 2).

We further postulate that socio-ecological factors play an important role in optimal treatment allocation. More precisely, we hypothesize that an algorithm including socio-ecological variables will perform significantly better than an algorithm without these predictors (Study B, Hypothesis 3).

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 16/09/2025, Bielefeld University Ethics Review Board (Office U4-132, Main Building, Universitätsstraße 25, Bielefeld, 33615, Germany; +49 (0)521 106-4468; ethikkommission@uni-bielefeld.de), ref: EUB2024-200-Am2

2. approved 09/10/2025, Lacor Hospital Institutional REC (St Mary's Hospital, PO Box 180, Gulu, -, Uganda; +256 (0)7725617 83; lacor.research@lacorhospital.org), ref: LACOR-2025-2131

Study design
Single-centre interventional outcome-assessor-blinded randomized controlled trial

Primary study design
Interventional

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Posttraumatic Stress Disorder (PTSD)

Interventions
Eligible participants will be randomized using block randomization stratified by mental health worker, ensuring that each mental health worker treats an approximately equal number of participants in each treatment condition.

We will randomize participants to two Active Comparators: Narrative Exposure Therapy (NET) & Extended Problem Management Plus (PM+).

1. NET is a short-term, evidence-based intervention to treat survivors of multiple trauma. The main aim of NET is to integrate and contextualize the defragmented trauma memories into a chronological narrative (Schauer et al., 2011, 2025). The NET treatment will consist of eight individual sessions (~90 minutes each, conducted twice a week) according to the treatment manual (Schauer et al., 2011, 2025). The first session will comprise psychoeducation as well as the lifeline exercise, which serves to obtain a chronological overview of the life of the client. In the following six sessions, the life events of the client will be narrated. Thereby, the therapist will guide the client to narrate the traumatic events in detail, including the emotional, sensory, cognitive, behavioral, and body memories, and contextualize these memories by elaborating details regarding time and space. The final session will summarize the narrated life events and review the NET process.

2. PM+ is a WHO-recommended, transdiagnostic approach developed to help communities facing adversity. In the development of PM+ international experts selected behavioral therapeutic strategies with a high evidence base (Dawson et al., 2015). For this study, the

original PM+ manual was adapted and extended to eight sessions in order to fit best to the local context of Northern Uganda. This is referred to as extended PM+. The Extended PM+ treatment will consist of eight individual sessions (~90 minutes each, conducted twice a week) according to the treatment manual, which has been adapted to the local context. The sessions will include psychoeducation, stress management (session 1), problem management (session 2+3), behavioral activation (session 4), managing daily stressors (session 6), social support (session 7), managing anger (session 7) and relapse prevention (session 8).

Both treatments will be provided by intensively trained non-specialist mental health workers with substantial experience in mental health and psychosocial support.

The primary outcome will be analyzed by means of linear mixed models with the PSSI-5 as the outcome variable, and time, group as well as their interaction as fixed effects.

The secondary outcomes will be also analyzed by means of linear mixed models with time, group as well as their interaction as fixed effects.

Intervention Type
Behavioural

Primary outcome(s)
PTSD symptom severity measured using the Posttraumatic Stress Disorder Symptom Scale Interview for DSM-5 (PSSI-5) sum score at baseline and 3 and 12 months after randomization

Key secondary outcome(s))
1. Depressive symptom severity measured using the sum score of the 9-item version of the patient health questionnaire (PHQ-9) at baseline and 3 and 12 months after randomization
2. Anxiety symptom severity measured using the GAD-7 sum score at baseline and 3 and 12 months after randomization

Completion date
31/07/2028

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years
2. Survivor of trauma related to the LRA conflict or ongoing violence in the post-conflict setting
3. Probable diagnosis of PTSD according to DSM-5 (PSSI-5)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Clinical signs of acute psychosis
2. Clinical signs of mental retardation that would interfere with psychosocial interventions
3. High alcohol abuse (AUDIT score >= 8) constitutes an exclusion criterion if the client is not willing and confident to be able to reduce the consumption during treatment
4. Drug abuse
5. Concurrent psychotherapy
6. Medication with benzodiazepines, as this medication might interfere with exposure-based psychotherapy (Singewald et al., 2015)
7. Acute risk of suicidality/ endangerment of others that would require immediate hospitalization of the client

Date of first enrolment
23/11/2025

Date of final enrolment
31/05/2028

Locations

Countries of recruitment
Uganda

Study participating centre
Vivo outpatient clinic for survivors of violence and torture
Adere Road, Plot 16
Gulu
Uganda
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Sponsor information

Organisation
Klinische Psychologie und Psychotherapie

ROR
https://ror.org/02hpadn98

Funder(s)

Funder type
Government

Funder Name
Deutsche Forschungsgemeinschaft (German Research Foundation, DFG)

Alternative Name(s)
German Research Association, German Research Foundation, Deutsche Forschungsgemeinschaft (DFG), DFG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Schweizerischer Nationalfonds zur Förderung der Wissenschaftlichen Forschung

Alternative Name(s)
Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The anonymised datasets analysed during the current study will be stored in a publicly available data repository (probably at osf, https://osf.io).

Type of data: anonymised IPD data

Intention to publish data date: 31/08/2029 (together with publication). The data will be stored permanently open access. Consent for sharing IPD data was obtained from participants.

Before sharing the data, the data will be anonymised (this included checking for rare or unique data points that might identify participants. Such data will be removed or aggregated in the anonymisation process).

The IPD data will be stored together with rich metadata and the analytic code that was used for the analyses of the publications.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes