ISRCTN86825441 https://doi.org/10.1186/ISRCTN86825441

Addressing leprosy trauma using the traumatic stress relief programme: an exploratory trial with persons with lived experience in Addis Ababa, Ethiopia

Submission date
30/08/2024

Recruitment status
No longer recruiting

Registration date
05/09/2024

Overall study status
Ongoing

Last Edited
18/03/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Leprosy is a chronic infectious disease that causes significant emotional and psychological distress. This study aims to help people who have lived with leprosy by offering a special programme designed to reduce stress and improve mental well-being. The programme is called the Traumatic Stress Relief (TSR) programme. This study aims to see if the TSR programme helps reduce stress and improve the overall mental health and quality of life for people with leprosy.

Who can participate?
People aged 18 years and over who have lived with leprosy

What does the study involve?
Participants will be randomly divided into two groups. One group will receive the TSR programme, which includes several therapy sessions over a set period. The other group will receive the usual care for leprosy without the extra TSR programme. The programme and observation will last a few weeks, with follow-up assessments to see how things are going after the programme ends.

What are the possible benefits and risks of participating?
Participants in the intervention group may experience improved mental health outcomes, with reductions in symptoms of PTSD, anxiety, and depression due to structured support and coping strategies provided during the TSR sessions. The group setting and involvement of peers with lived experience can enhance social support, improving awareness and education about leprosy, potentially reducing self-stigma and promoting better self-management. Participants also gain access to psychological resources that might not be otherwise available, contributing to research that could lead to better future treatments and influencing policy changes.

The study's findings may demonstrate how peer-delivered interventions can serve as a primary strategy to enhance health outcomes in the short term, focusing on sustainable mental health

benefits. Such interventions can be cost-effective and widely acceptable, improving health and mental health for current and future generations and enhancing human capital. When findings are translated to other groups, they could benefit a broader population.

However, risks are involved, including emotional discomfort from discussing personal experiences, the time commitment required to attend multiple sessions, and concerns about privacy in a group setting. Additionally, there's a possibility that the intervention might not be as effective for some participants, which could lead to disappointment. Managing these risks involves thorough informed consent processes, rigorous confidentiality maintenance, and providing emotional support during and after the intervention sessions. Participants should also be free to withdraw from the study at any point without any penalty.

Where is the study run from?
Boğaziçi University, Istanbul

When is the study starting and how long is it expected to run for?
January 2024 to December 2025

Who is funding the study?
Leprosy Research Initiative

Who is the main contact?
Dr Safa Kemal Kaptan, safa.kaptan@bogazici.edu.tr

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Safa Kemal Kaptan

ORCID ID
https://orcid.org/0000-0002-4709-6543

Contact details
Boğaziçi University, Istanbul
Istanbul
Türkiye
34846
+90 212 359 73 24
safa.kaptan@bogazici.edu.tr

Type(s)
Scientific

Contact name
Mr Marekegn Habtamu

Contact details

Woreda 2
Addis Ababa
Ethiopia
Woreda 2
+251-912-12345
MarekegnH@tlmethiopia.org

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
FP24.11

Study information

Scientific Title
An exploratory trial evaluating the traumatic stress relief programme in individuals with leprosy in Addis Ababa, Ethiopia

Acronym
LEAP-TSR

Study objectives
Primary Hypothesis: Participants with leprosy who undergo the Traumatic Stress Relief Programme will show a significant reduction in symptoms of traumatic stress compared to those who do not receive the intervention.

Secondary Hypothesis: The Traumatic Stress Relief Programme will lead to improvements in overall mental health and quality of life for individuals with leprosy.

Exploratory Hypothesis: The effectiveness of the Traumatic Stress Relief Programme may vary based on the severity of leprosy symptoms and the duration of the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/08/2024, City Government of Addis Ababa Health Bureau (Bole Subcity, Addis Ababa, 30738, Ethiopia; +251115153939; aahb@ethionet.et), ref: A/A 1340/227

Study design
Explanatory randomized controlled trial

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Leprosy related trauma and mental health difficulties

Interventions
The study employs a randomized controlled trial design to evaluate the effectiveness of the Traumatic Stress Relief (TSR) intervention for individuals affected by leprosy in Addis Ababa, Ethiopia. The methodology for each study arm is as follows:

Intervention Group
Participants in the intervention group receive the TSR intervention. This group attends three group sessions, which are delivered over approximately three weeks. Each session lasts between 60-90 minutes and is conducted in person at a designated location in Addis Ababa. The sessions aim to address the psychological and social impacts of leprosy, focusing on reducing symptoms of PTSD, anxiety, and depression while enhancing social support. Sessions are facilitated by a pair, consisting of a mental health professional and a peer with lived experience of leprosy. The facilitators use a detailed protocol and checklist, ensuring consistency and effectiveness in the delivery of the intervention.

Control Group
Participants in the control group are placed on a waitlist and do not receive the TSR intervention during the active phase of the study. They continue to receive routine care as provided by local health services. Following the conclusion of the study's primary follow-up period, they are offered the TSR intervention, thereby addressing ethical considerations and maintaining participant engagement.

Duration of Treatment
The total duration of the intervention for the TSR group is three weeks, encompassing three sessions. Follow-up assessments for both groups are conducted immediately post-intervention to evaluate both the short-term and long-term effects of the intervention.

Randomization Process
Randomization is conducted by an independent, off-site statistician to ensure allocation concealment and minimize selection bias. Participants are randomized in a 1:1 ratio to either the intervention or control group. The randomization sequence is generated using computerized software and participants are allocated accordingly.

Intervention Type
Behavioural

Primary outcome(s)
Level of traumatic stress measured using the International Trauma Questionnaire (ITQ) before and after the sessions

Key secondary outcome(s))
1. The severity of depressive symptoms and overall mental health measured using the Patient Health Questionnaire-9 (PHQ-9) at baseline and immediately post-intervention

2. The severity of anxiety symptoms measured using the Generalized Anxiety Disorder-7 (GAD-7) at baseline and immediately post-intervention
3. Quality of Life measured using the EQ-5D-5L (EuroQol Five-Dimensional Scale), including participants' mobility, self-care, usual activities, pain/discomfort, and anxiety/depression at baseline
4. The level of social support and the extent of participants' social networks measured using the Oslo Social Support Scale (OSSS-3) at baseline
5. Perceived stigma associated with having leprosy measured using the 5-Question Stigma Indicator - Affected People (5-QSI-AP) at baseline
6. Participants' perceptions of the acceptability and feasibility of the Traumatic Stress Relief Programme measured using the TFA Acceptability Questionnaire immediately post-intervention

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. A lived experience of leprosy
2. Aged 18 years old and over
3. Able to provide informed consent, indicating they understand the study's purpose, procedures, and potential risks
4. Reside in or have access to the study site in Addis Ababa, Ethiopia, for the duration of the intervention
5. Able to understand and communicate in Amharic

Participant type(s)
Patient, Resident, Population, Service user

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Individuals who do not have a lived experience of leprosy will be excluded from the study
2. Aged under 18 years old
3. Unable to provide informed consent due to cognitive or other impairments will be excluded. Informed consent must indicate an understanding of the study's purpose, procedures, and potential risks.
4. Do not reside in or have access to the study site in Addis Ababa, Ethiopia
5. Unable to understand and communicate in Amharic will be excluded, as this is necessary for effective participation in the study

Date of first enrolment
01/11/2024

Date of final enrolment
01/12/2025

Locations

Countries of recruitment
Ethiopia

Study participating centre
Leprosy Mission Ethiopia
nifas silk Lafto, woreda 02, BWTC building,
2nd Floor- 202, 203 & 211
Addis ababa
Ethiopia
Woreda 02

Sponsor information

Organisation
Leprosy Research Initiative

Funder(s)

Funder type
Charity

Funder Name
Leprosy Research Initiative

Alternative Name(s)
The Leprosy Research Initiative, Lepra Research Initiative, Iniciativa de investigación de la lepra, Iniciativa de Pesquisa em Hanseníase, Inisiatif Penelitian Kusta, , , LRI

Funding Body Type
Private sector organisation

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

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Safa Kemal Kaptan, safa.kaptan@bogazici.edu.tr. This will include all quantitative and qualitative data once the results are published.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/03/2025	18/03/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes