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Lay counselor-facilitated thought field therapy (TFT) for internally displaced women in Iraq

Submission date
20/06/2023

Recruitment status
No longer recruiting

Registration date
10/08/2023

Overall study status
Completed

Last Edited
03/03/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
In this study, Dr. Pegah Seidi and her team aim to train women without professional medical or mental health backgrounds to become lay counselors for trauma-related disorders. Overall, this study aims to train lay counselors to provide treatment for trauma-related disorders in IDP camps, with a focus on comparing the effectiveness of TFT interventions and stress-reduction exercises. The study follows ethical guidelines, including informed consent, confidentiality, and monitoring of adverse experiences, and includes assessments conducted by blinded assessors.

Who can participate?
Women over the age of 18 years residing in either the Tazade IDP Camp or the Qurato IDP Camp who are self-reporting symptoms of trauma such as anxiety, depression, anger, feelings of guilt, flashbacks, and/or intrusive memories and are not diagnosed with a serious mental illness such as schizophrenia, psychosis, or OCD.

What does the study involve?
Volunteers will be randomly divided into two groups: Group 1 and Group 2. Group 1, consisting of a larger number of volunteers, will be trained in facilitating TFT (Thought Field Therapy) interventions, while Group 2, with a smaller number of volunteers, will be trained in stress-reduction exercises such as 4-7-8 breathing and progressive muscle relaxation. Training materials will be translated into English, Arabic, and Kurdish.

The participants will be recruited from two internally displaced persons (IDP) camps: Tazade IDP Camp and Qurato IDP Camp. The camps will be randomly allocated to either Group 1 or Group 2 to minimize cross-contamination. The opportunity to participate in the study will be announced on official research center and hospital pages, as well as by the principal investigator.

The newly trained lay counselors will provide treatment to participants in both camps for trauma-related symptoms over six days, allowing for three treatment sessions per participant. The counselors will be supervised by the principal investigator and her team. Posttest data will be collected one week after the last treatment session, and a follow-up assessment will take place one month later.

What are the possible benefits and risks of participating?
The benefits to women taking part in this study are that they may experience diminished symptoms of trauma and general health benefits.
The risks to women taking part in this study include, remembering present or past experiences that might make them feel sad or unhappy during the assessments or interventions.

Where is the study run from?
University of Garmian (Iraq)

When is the study starting and how long is it expected to run for?
March 2023 to August 2023

Who is funding the study?
Thought Field Therapy Foundation (USA)

Who is the main contact?
Pegah Seidi, Pegah.am.seidi@kti.edu.iq
Suzanne M Connolly, smc@suzanneconnolly.com

Study website
https://lc-tft.org/

Contact information

Type(s)
Principal Investigator

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effectiveness of lay counselor-delivered thought field therapy for trauma-related symptoms among trauma-affected internally displaced women in Iraq

Acronym
LC-TFT

Study objectives
Our hypothesis is that professionally trained lay counselors who have been professionally trained to facilitate thought field therapy (TFT) interventions can efficiently and effectively reduce symptoms of trauma in themselves and women living in ID Camps.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/06/2023, Research Center of Garmian Ethics Committee (Bardesur, M923+CR7, Kalar, 62021, Iraq; +964 7726597127; info@garmian.edu.krd), ref: 0105

Ethics approval is available as Appendix AA. Note: All appendices are available at https://lc-tft.org

Study design
Double-blind computer-generated cluster-randomized controlled interventional study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life, Treatment, Efficacy

Participant information sheet
There are three information sheets for participants. The first is the consent to take part which is given before the allocation of the Camps to either Group 1 or Group 2. (Appendix D). There are two versions of the second which describe what treatment they will receive in the treatment group they are allocated to (Appendices H and I). Note: All appendices are available at https://lc-tft.org/

Health condition(s) or problem(s) studied
Reduction of posttraumatic stress symptoms in women living in IDP camps in Iraq

Interventions
Note: All appendices are available at https://lc-tft.org/
The study will begin with a public announcement inviting women over the age of 18 who are not employed as professional medical or mental health professionals to attend a training course on treating trauma-related disorders. Up to twenty women (depending on the response) will be selected by Dr.Pegah Seidi, the principal investigator, and her assistants. After accepting the invitation and signing a letter of acceptance (Appendix A), those volunteering to become lay counselors will then be randomly divided into two groups of equal size using a random allocation software program selected by the statistician. After being allocated to either Group 1 or Group 2 arm of the study, each group of lay counselors will be informed as to which group they have been assigned to and asked to sign an informed consent detailing the treatment they will be trained in (Appendices B & C).

Group 1 will consist of up to volunteers who will learn to facilitate TFT interventions and Group 2 will consist of ten volunteers that will learn to facilitate two different stress-reduction interventions. Group 1 will attend a TFT training. Group 2 training in the use of stress-reduction exercises (4-7-8 breathing and progressive muscle relaxation). All material will be translated into English, Arabic, and Kurdish.

The participants will be recruited from two camps for internally displaced persons (IDPs); the Tazade IDP Camp, and the Qurato IDP Camp. The camps will be randomly allocated to either Group 1 or Group 2 by a computer program. The camps are geographically distant enough to reduce cross-contamination. The opportunity for women in either of the two chosen camps will be announced on the official pages of the Research Center, Life Hospital (host of the training sessions), and by the principal investigator (Pegah Seidi). The principal investigator will accept the first 100 volunteers from each camp who meet the inclusion criteria to take part in the study, for a total of 200 volunteer participants. Prior to treatment, the 200 participants will sign the informed consent form to take part in the study (Appendix D). and fill out the PCL-C (Appendix E), the GHQ-28 (Appendix F), and the demographic questionnaire (Appendix G), which have been previously professionally translated into their native languages.

After Camps are allocated to two groups, on the first day of treatment, participants in each group will sign the informed consent form that describes the form of treatment they will be receiving. (Appendices H & I). The information in the letters will additionally be thoroughly explained to the participants in their own language through professional translators. The participants will also be informed that if at the end of the study, one of the two interventions offered is found to be more effective than the other intervention, they will have an opportunity, following the end of the study, to be treated with the more effective intervention. They will be advised of the adverse experience form (Appendix J) should they experience any adverse experiences as a result of taking part in the study. The assessments will be conducted by Garmian University graduate students who will have received instructions for gathering the pretest, posttest, and follow-up data. The assessors will be blind to which treatment is being considered by the researchers to be the treatment group and which group is considered by the researchers to be an active waitlist group. There will be four assessors working in the field for three days: one day for pretesting, one day for post-testing, and one day for follow-up assessments. The assessors will help anyone needing assistance to complete any of their forms. The only person having access to names and their coded numbers will be the principal investigator and she will keep this document in a separate locked file cabinet.

Participants in both camps will be treated for their trauma-related symptoms by the newly trained lay counselors using their allocated interventions over the course of six days. This will allow 3 treatments for each participant. The principal investigator and her assistants will supervise the newly trained lay counselors as they treat the participants. One week following their last treatment, participants will be invited to come back at the same time of the day as they took their pretest test in order to gather posttest data. The therapists will keep a record of whom they treat (by code number only) for what problem, how many minutes it took, and a beginning and ending Subjective Units of Distress (SUD) (0-10) score on a prepared form (Appendix K). The follow-up will take place one month later for both group 1 and group 2 by the same facilitators.

Intervention Type
Behavioural

Primary outcome measure
Symptoms of traumatic stress as self-assessed on PCL-C at baseline, posttest, and follow-up

Secondary outcome measures
Quality of life as self-assessed on the Quality-of-Life Scale (GHQ-28) at baseline, posttest, and follow-up

Overall study start date
05/03/2023

Completion date
18/08/2023

Eligibility

Key inclusion criteria
1. Women over the age of 18 years
2. Residing in either the Tazade IDP Camp or the Qurato IDP Camp
3. Self-reporting symptoms of trauma such as anxiety, depression, anger, feelings of guilt,

flashbacks, and/or intrusive memories
4. Not diagnosed with a serious mental illness such as schizophrenia, psychosis, or OCD.

Participant type(s)
Resident, Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Female

Target number of participants
200 participants, 2 clusters of 100 each

Total final enrolment
200

Key exclusion criteria
1. Not living in either the Tazade IDP Camp or the Qurato IDP Camp
2. Under the age of 18 years
3. Male
4. Diagnosed with a serious mental illness such as schizophrenia, psychosis, OCD
5. Not reporting symptoms of traumatic stress.

Date of first enrolment
15/06/2023

Date of final enrolment
21/06/2023

Locations

Countries of recruitment
Iraq

Study participating centre
Research Center, University of Garmian
Bardesur, M923+CR7
Kalar
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/04rc8af74

Funder(s)

Funder type
Charity

Funder Name
Thought Field Therapy Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
The database will be stored in a database available to the public at https://lc-tft.org/

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			03/03/2025	No	No