KURDISTAN REGIONAL GOVERNMENT-IRAQ

MINISTARY OF HIGHEREDUCATION & RESEARCH

PRESIDENCY OF GARMIAN UNIVERSITY

RESEARCH CENTER

Number: 0105 **Date:** June 15, 2023

Ethical Approval Application Form

1- Administration Details

Researcher(s):

Pegah AM Seidi, Suzanne Connolly, Dilshad Jaff, Linda Tawfik

School/Research Centre/Programme (as applicable):

Research Center, University of Garmian

Title of Project:

Effectiveness of lay counselor-delivered thought field therapy for trauma-related symptoms among trauma-affected Internally Displaced Women in Iraq.

Contact Email: Pegah.am.Seidi@garmian.edu.krd

Note: The lead researcher has an obligation to bring to the attention of the Research Centre Ethics Committee any issues with ethical implications not clearly covered by this application form.

2. Application form Checklist

Please complete the ethics application form below and provide additional information as attachments.

My application includes the following documentation:	**INCLUDED (mark as YES)**	**NOT APPLICABLE (mark as N/A)**
Recruitment advertisement	N/A	
Participant Information Leaflet		N/A
Participant Informed Consent form*		N/A
Questionnaire/Survey**	**Yes**	
Interview/Focus Group Questions		**N/A**
Debriefing material		**N/A**
Evidence of approval to gain access to off-site location	**Yes**	
Ethical Approval from external organizations.*** If ethical approval from external organizations is pending give details below	**Yes**	

Details:

*consent form is blind in this study
**Appendix D
*** This study is additionally being registered as an international randomized controlled trial on the ISRCTN website.

3. Project Details

a) Lay description (Maximum 200 words)

Please outline, in terms that any non-expert would understand, what your research project is about, including what participants will be required to do. Please explain any technical terms or discipline-specific phrases.

Study Purpose:

The purpose of this study is to determine if community members who have been professionally trained to facilitate Thought Field Therapy (TFT) interventions can efficiently and effectively facilitate TFT interventions to reduce symptoms of trauma experienced in members of their own community. The authors believe that it is important that a model for treating trauma be developed to effectively and efficiently address psychological trauma, a serious contributor to the global burden of disease, especially in underserved areas, and in particular in low and middle-income countries.

The lay counselors:

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 will be selected by Dr. Pegah Seidi, the principal investigator, and her assistants; Sherko Abdulla, Borhan Jaff, Somaya Esa, and Saya Esa. After accepting the invitation and signing a letter of acceptance to participate (Appendix A) The twenty selected volunteers 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 one arm of the study, each group of 10 lay counselors will be informed of which group they were assigned to and asked to sign an informed consent detailing the treatment they will be trained in and then facilitating (Appendices B). Group 1 will consist of ten volunteers that 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 two-week training in the use of TFT to treat symptoms of trauma, and other psychological problems resulting from exposure to traumatic events. Group 2 will attend a one-day 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 Random controlled Group-Cluster Study:

To prevent cross-contamination, this will be a cluster-random controlled trial and the two camps will be allocated to either group 1 or Group 2, by a computer-generated program selected by the statistician. The participants will be recruited from two camps for internally displaced persons (IDP's); the Tazade IDP Camp and the Qurato IDP Camp, located in proximity to the principal investigator. The camps are geographically distant enough, however, to reduce cross-contamination.

The participants:

The opportunity for women over 18 and who live in one of the two chosen camps will be announced on official pages of Research Center, Life Hospital (host of the training sessions) and by principal investigator (Pegah Seidi). The researchers will accept the first 100 volunteers from each camp to participate in the study for a total of 200 volunteer participants. Prior to the beginning of treatment, 200 participants will sign the informed consent form to participate in the study (Appendix C) and fill out the

PCL-5, GHQ, and demographic questionnaire which have been previously professionally translated into their native languages (Appendices D). The information in 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.

Assessments:

Pretesting, post testing, and follow-up assessments will be each be conducted by University of Garmian graduate students who will have received a day of 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 be compensated fifty dollars U.S. for travel, food, and water for each of the three days for a total of $150 U.S for each assessor. Four groups of 25 participants will arrive at two-hour intervals each day. There will be a 9 am group, an 11 am group, a 1 pm group, and a 3 pm group, allowing two hours for each group throughout the day. A volunteer community leader will greet the participants as they arrive and thank them for coming. Then, the researchers will give the participants instructions. The assessors will assist anyone needing assistance to complete any of their forms.

Confidentiality and risk-of-bias prevention: After the participants have completed their pretests, the researchers will place the participants' completed Consent Forms, Demographic Questionnaires, and pretests in the participants individual file folders and keep the file folders in a locked file cabinet for the duration of the study. The information gathered through the posttesting, follow-up, and additional forms collected will also be added to their files and kept in a locked file cabinet. No forms will have client names, only numbers. (The Consent Forms will be in duplicate, and the participants will keep a copy.)The only person having access to names and their coded numbers will be the principal investigator and she will keep this key in a separate locked file cabinet.

Method:

Following pretesting, 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 researchers will supervise the newly trained facilitators(lay-counselors) as they treat the participants. One week following their last treatment, participant will be invited to come back at the same time of the day as they took their pretest-test in order to gather post-test 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. The facilitators will be instructed on how to use this basic form during their initial training.

The follow-up will take place one month later for both group 1 and group 2 by the same facilitators. Participants in both groups will take the tests at the same days of the week at times of the day that they took their posttests. They will receive instructions again and be thanked for participating again.

b) Research objectives (Maximum 150 words)

Please summaries briefly the objectives of the research:

This study aimed to answer these questions:

1. *Will thought field therapy (TFT) delivered by lay-counselors significantly reduce trauma-related symptoms in internally displaced women when compared to the stress-reduction group?*
2. *Will thought field therapy (TFT) delivered by lay-counselors significantly reduce the self-reported SUD?*
3. *What will be the average TFT treatment times for participants in Group 1 and In group 2?*

c) Research location and duration

Location(s)/Population	**Kurdistan region of Iraq /Tazade and Qurato IDP camps**
Research start date	Jun 22nd
Research end date	**September 1st**
Approximate duration	3 months
Project Funder	TFT foundation

4. Participants

Participant Information	Yes	No	NA
Will you inform participants that their participation is voluntary? ×	*		
Will you inform participants that they may withdraw from the research at any time and for any reason?	*		
Will you inform participants that their data will be treated with full confidentiality and that, if published, it will not be identifiable as theirs?	*		
Will you provide an information sheet that will include the contact details of the researcher/team?	*		
Will you obtain written consent for participation?	*		
Will you debrief participants at the end of their participation (i.e., give them an explanation of the study and its aims and hypotheses)?	*		

Will you provide participants with written debriefing (i.e., a sheet that they can keep that shows your contact details and explanations of the study)?			*
If using a questionnaire, will you give participants the option of omitting questions that they do not want to answer?	*		
If an experiment, will you describe the main experimental procedures to participants in advance, so that they are informed about what to expect?			*
If the research is observational, will you ask participants for their consent to being observed?			*

*Please attach a copy of 'Consent Form' and any relevant form to be provided to the participant(s) to enable informed consent.

5. Sample details

Approximate number	200
Where will participants be recruited from?	*IDP camps(Qurato, Tazade).*
Inclusion Criteria	*Lay counselors:* *- Educated (finished high school)* *- volunteers and community workers* *Participants:* *-Women* *- Living in IDP camps* *- having granted free consent* *- +18 years' old* *- Reposting PTSD or Trauma related symptoms* *- experiencing trauma* *- being forcibly removed from their homes*
Exclusion Criteria	Lay-counselors: *- Mental health professionals,* *-Medical professionals (including CHW's)*

	Participants: - *<18 years* - *Diagnosed by specific mental health disorders (like OCD, MD, ...)*
Will participants be remunerated, and if so in what form? No	

Justification for proposed sample size and for selecting a specific gender, or any other group if this is done in your research.

The study will be conducted in Sulaymaniyah province, in the Tazade and Qurato camp that is populated by IDP families. These are the regions of Iraq where most of the extremely traumatized and marginalized IDP communities are located. Many others within this population of IDPs have been displaced to cities, towns, and residential complexes in Sulaymaniyah and other provinces. It is estimated that 63% of the total IDP population are not living in formal camps. We are limiting the pilot study to women and hope to be able to replicate this study in the future with a mixed population.
For two groups (immediate treatment group and active wait list group) the number of participants is 200 women (100 in each group). They will be +18 years old, who have volunteered to receive a brief treatment for symptoms of trauma. All participants will be members of IDP society who have escaped from ISIS fighters and live in one of the two camps. All participants will be selected according to the self-report of suffering from symptoms of trauma. The TFT group will compare to the stress-reduction group one week and one month following their intervention to determine if TFT will produce changes significantly greater than the stress-reduction group.

6. RISKS TO PARTICIPANTS

a) Please describe any risks to participants that may arise due to the research. Such risks could include physical stress, emotional distress, perceived coercion e.g. lecturer interviewing own students. Detail the measures and considerations you have put in place to minimize these risks.

For TFT group 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. For the stress reduction group, the risks might be that they may think about difficult things while doing the 4-7-8 exercise or during the assessment and temporarily feel some emotional upset. In these cases, the researchers (the clinical psychologists) will be on-site for the two weeks of the study and one-week post study to provide crisis counseling. Local referrals for mental health counseling will also be provided to you. Any adverse experiences will also be recorded (Appendix E).

b)What will you communicate to participants about any identified risks? Will any information be withheld from them about the research purpose or procedure? If so, please justify this decision.

All participants will be informed of risks (Appendices C) and the opportunity to report any adverse experiences. They will all be told they are in a treatment group, which is true, however the study is designed with the idea that TFT is the treatment group, and the stress-reduction group is the active waitlist group. In any case they both get treatments.

Please outline your approach to ensuring the confidentiality of data (that is, that the data will only be accessible to agree upon parties and the safeguarding mechanisms you will put in place to achieve this.) You should include details on how and where the data will be stored, and who will have access to it.

Only the camp managers and staffs who informed women, have access to participants names. The camp managers will not have access to client's numbers. Excluding the principle investigator, others involved in the study will see only the client numbers. Also, the assessors will not have access to participants' names, only their assigned number. No one else at the University or anywhere will ever see their questions and answers. Only a statistician will be seeing their questions and answers, but she will not have access to their name, only their assigned number. All information will be kept in a locked cabinet and its key will be kept in a locked file cabinet. Data will be stored as an online file on Google drive of principal investigator and also in the archives of Research Center at the University of Garmian.

Please outline how long the data will be retained for, if it will be destroyed and how it will be destroyed.

This data will be kept in a locked file cabinet at Garmian University and then destroyed ten years after the end of the study

7. Declaration

I have read and understand the guidelines for ethical practices in research and have read and understand the data protection guidelines.

Signed: **Name:** Pegah A.M Seidi

Date: **May 10th, 2023**

(Researcher)

8. STATEMENT OF ETHICAL APPROVAL

To whom it may concern

As a ethical committee of Research Center, Garmian University, we certify that the project entitled ‘’ *Effectiveness of lay counsellor-delivered thought field therapy for trauma-related symptoms among trauma affected Internally Displaced Women in Iraq***’’ has been considered using agreed procedures and is now approved.**

This committee strictly adheres to ‘‘Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants’’ and ‘‘Australian Code of Practice for the Care and Use of Animals for Scientific Purposes’’.

Chair of Ethics Committee

This project has been considered by the Ethics Committee and ethical approval is granted.

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Signed: _____ **Name:** Ayad Palani

Date: June 15, 2023