

A study to test whether a group EMDR therapy can reduce war-related stress in displaced people in Lebanon

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|--------------------------|----------------------------------|---|
| Submission date | Recruitment status | <input type="checkbox"/> Prospectively registered |
| 03/05/2025 | No longer recruiting | <input type="checkbox"/> Protocol |
| Registration date | Overall study status | <input type="checkbox"/> Statistical analysis plan |
| 21/05/2025 | Completed | <input type="checkbox"/> Results |
| Last Edited | Condition category | <input type="checkbox"/> Individual participant data |
| 19/08/2025 | Mental and Behavioural Disorders | <input checked="" type="checkbox"/> Record updated in last year |

Plain English summary of protocol

Background and study aims

This study is exploring how effective a type of group therapy called EMDR (Eye Movement Desensitization and Reprocessing) is in helping young Lebanese adults cope with anxiety, depression, PTSD, and emotional distress. The focus is on people who were forced to leave their homes during the 2024 Israeli war on Lebanon and who may also be affected by trauma passed down from the Lebanese civil war.

Who can participate?

The study is looking for 70 Lebanese adults between the ages of 18 and 34 who were born after the civil war ended in 1991. To take part, they must have lived in Lebanon since 2019 and have been displaced from their homes due to the 2024 war. They also need to show signs of anxiety, depression, or PTSD. People who were displaced before the major attacks in September 2024, who moved into homes they already owned, or who were diagnosed with mental health conditions in the two years before the war are not eligible. Others who cannot take part include those currently receiving mental health treatment, those with serious mental health issues such as psychosis or suicidal thoughts, and those with substance dependency or severe cognitive difficulties.

What does the study involve?

People who took part in an earlier related study and agreed to be contacted again will be invited by phone. If they agree to join, they will be randomly placed into one of two groups. One group will receive the therapy right away, while the other will wait two weeks before starting. The therapy involves four sessions over two days, with each session lasting between one and a half to two hours. Before starting, participants will be screened in person to make sure they meet the study's requirements. They will also be asked to complete short online questionnaires before and after the therapy, and again one month later. These questionnaires will ask about symptoms of anxiety, depression, PTSD, and emotional distress related to trauma passed down from the civil war.

What are the possible benefits and risks of participating?

Participants will receive free therapy that may help them manage trauma and emotional distress. The study also helps researchers learn more about how well this therapy works for people affected by war and inherited trauma. However, answering questions or taking part in therapy may bring up upsetting memories or feelings. Participants can skip any question or stop at any time. Support will be available during and after the sessions, including one-on-one help if needed. All personal information will be kept private and secure, and only general findings will be shared in reports or publications.

Where is the study run from?

The therapy sessions will take place at community centers in Beirut, Beqaa, and South Lebanon. All questionnaires will be completed online.

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

March 2025 to July 2025

Who is funding the study?

This study is part of a PhD project and is not receiving any outside funding.

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CEC: 46/ 19.03.2025

Study information

Scientific Title

Effectiveness of EMDR Group Traumatic Episode Protocol (G-TEP) in reducing war-related distress among internally displaced Lebanese: a randomized controlled trial

Acronym

G-TEP RCT

Study objectives

Hypothesis 1: EMDR G-TEP is effective in reducing war-related trauma symptoms (anxiety, depression, PTSD/CPTSD) among internally displaced second-generation Lebanese descendants

Hypothesis 2: EMDR G-TEP is effective in reducing psychological distress related to intergenerational trauma from the Lebanese Civil War among internally displaced second-generation Lebanese descendants

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 19/03/2025, The Scientific Research Ethics Committee of the University of Bucharest (Academic Street, Nr.14, Sector 5, Bucharest, 010014, Romania; +40213059730; cometc@unibuc.ro), ref: CEC:138/19.03.2025

Study design

Multicenter interventional open label randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Efficacy

Health condition(s) or problem(s) studied

EMDR intervention addressing symptoms of anxiety, depression, PTSD, complex PTSD and psychological distress related to intergenerational trauma from the Lebanese civil war in a sample of internally displaced Lebanese individuals.

Interventions

This study is a follow-up study (study II) to a previous study (study I) on the prevalence of anxiety, depression, PTSD/CPTSD. It is noteworthy that the data collection for study I (the prevalence study) had been completed. Participants who completed study I and who were found to have a comorbid anxiety and depression, and/or PTSD/CPTSD, and indicated their willingness to be contacted for this follow-up study (study II) will be invited by phone to participate in this study. During the phone conversation, each participant will be assigned a unique study code and asked to read the information sheet and provide consent to participate in the study. The LimeSurvey link to the information sheet and informed consent form will be sent to each participant directly the phone call.

Upon their consent to participate, participants, in each of the three strata (Beirut, Beqaa, and South Lebanon), will be randomly assigned to one of two groups: an immediate intervention group or a delayed treatment control group. It is important to note that on the day of the intervention, participants will be asked to complete an initial eligibility screening in person. This brief 10-minute screening will be conducted by the research team using a standardized set of questions adapted from the Structured Clinical Interview for DSM-5 (SCID-5), along with additional items informed by standard clinical practice. The purpose of this screening is to determine whether each participant meet any of the study's exclusion criteria, which include the presence of psychotic symptoms, current treatment (e.g., psychotropic medications or psychotherapy), active suicidal ideation, alcohol or substance dependence, or severe cognitive impairment. If any of these exclusion criteria are met, this participants will not proceed with the intervention; however, they will be provided with a list of free or low-cost mental health resources in Lebanon to support them. If none of the exclusion criteria are met, they will be eligible to continue with the study as planned.

- **Immediate Intervention Group:** If the participant was assigned to the immediate intervention group, they will participate in EMDR group therapy with up to 12 participants over four sessions, held across two consecutive days (two sessions per day). Each session will last between 1.5 and 2 hours. Two weeks after the final EMDR session, this participant will be asked to complete an online post-test questionnaire (T1) via Lime Survey, which will measure symptoms of anxiety using the GAD-7, depression using the PHQ-9, PTSD/CPTSD using the ITQ, and psychological distress related to intergenerational trauma from the Lebanese civil war. One month after the post-test, this participant will be asked to complete a follow-up questionnaire online (T2) via Lime Survey, which will also assess symptoms of anxiety, depression, PTSD/CPTSD, and psychological distress related to intergenerational trauma from the Lebanese civil war, using the same questionnaires. We estimate that completing these measures at T1 and T2 will take 8-10 minutes each. Please note that this study includes a total of three immediate intervention groups, one in Beirut, one in South Lebanon, and one in the Beqaa region, each consisting of up to 12 participants.
- **Delayed Treatment Group:** If the participant was assigned to the delayed treatment group, they will be asked to wait for two weeks without receiving any intervention. After this waiting period, they will be asked to complete a pre-test online questionnaire (T0) via Lime Survey, measuring symptoms of anxiety using the GAD-7, depression using the PHQ-9, PTSD/CPTSD using the ITQ, and psychological distress related to intergenerational trauma from the Lebanese civil war. Following the pre-test, this participant will participate in the EMDR group therapy with up to 12 participants over four sessions, held across two consecutive days (two sessions per day). Each session will last between 1.5 to 2 hours. Two weeks after the final EMDR session, they will be asked to complete an online post-test questionnaire (T1), which will measure symptoms of anxiety, depression, PTSD/CPTSD, and psychological distress related to intergenerational trauma from the Lebanese civil war, using the same questionnaires. One month after the post-test, they will be asked to complete a follow-up questionnaire online (T2) via Lime Survey, which will also assess symptoms of anxiety, depression, PTSD/CPTSD, and psychological distress related to intergenerational trauma from the Lebanese civil war, using the same questionnaires. We estimate that completing these measures at T0, T1, and T2 will take 8-10 minutes each. Please note that this study includes a total of three delayed treatment groups, one in Beirut, one in South Lebanon, and one in the Beqaa region, each consisting of 12 participants.

The co-investigator, Mrs. Charlotte El Khalil, who will be responsible for administering EMDR G-TEP in this study, is a licensed psychologist and psychotherapist in Lebanon, and an EMDRIA (EMDR International Association) Certified Therapist. Mrs. El Khalil is also trained in administering EMDR Group Traumatic Episode Protocol (G-TEP). Notably, two facilitators, also licensed clinical psychologists, will accompany Mrs. El Khalil during the EMDR intervention.

Intervention Type

Behavioural

Primary outcome(s)

1. Anxiety symptoms (measured by the GAD-7)
2. Depression symptoms (measured by the PHQ-9)
3. PTSD/CPTSD symptoms (measured by the International Trauma Questionnaire [ITQ])
4. Psychological distress related to intergenerational trauma from the Lebanese civil war (measured using a modified version of the Historical Intergenerational Trauma Questionnaire [HITT-Q]).

Participants completed these measures as part of a previous prevalence study (baseline data). Participants in the delayed treatment group will complete a pre-test (T0) using the same measures after a two-week waiting period. Both the immediate intervention group and the delayed treatment group will complete a post-test (T1) two weeks after the final intervention session, and a follow-up assessment (T2) one month after the post-test, using the same set of measures.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

10/07/2025

Eligibility

Key inclusion criteria

1. Lebanese nationality
2. Adult, born after the end of the civil war (1991 and beyond), aged between 18 and 34 years
3. Residing in Lebanon for the past six years (i.e., from 2019 to the present)
4. Displaced from their home due to the recent Israeli war on Lebanon, which escalated in September 2024
5. Had scores indicative of comorbid anxiety and depression and/or PTSD/CPTSD

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

34 years

Sex

All

Total final enrolment

70

Key exclusion criteria

1. Experiencing displacement between October 8th, 2023, and August 2024, during the Israeli strikes on villages along the Lebanese border, prior to the large-scale Israeli strike across Lebanon that began in September 2024
2. During displacement, moving to a house that you own in the area of displacement

3. Having been diagnosed by a mental health professional (psychologist or psychiatrist) with depression, anxiety, or PTSD/CPTSD within the two years prior to the escalation of the Israeli war on Lebanon in September 2024
4. Active psychotic symptoms
5. Currently receiving treatment such as medication, psychotherapy, or similar interventions
6. Active suicidal ideation
7. Alcohol/substance dependency
8. Severe cognitive impairment

Date of first enrolment

20/03/2025

Date of final enrolment

30/04/2025

Locations

Countries of recruitment

Lebanon

Study participating centre

Online

Lebanon

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Sponsor information

Organisation

University of Bucharest

ROR

<https://ror.org/02x2v6p15>

Funder(s)

Funder type

Other

Funder Name

investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary

Published as a supplement to the results publication

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 |