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Investigating disruptive, healthy and brain electrical activity responses to effective psychological trauma treatments

Submission date
26/04/2021

Recruitment status
No longer recruiting

Registration date
21/05/2021

Overall study status
Completed

Last Edited
06/06/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

What is the aim of the study?
A trauma is a difficult life event, which causes upset to the present day and can be difficult to talk about. Fortunately, there are psychotherapies that work to understand what happened, in order for patients to feel at peace and be better. This study aims to understand how patients respond to effective psychological treatment for trauma and why they respond that way.

Who can participate?
Patients from the Center of Applied Psychology of the University of Talca, between 18 and 59 years old and who have been exposed to at least one difficult or traumatic event.

What does the study involve?
Each participant will receive one of two therapies that work for psychological trauma. The participant will be allocated to receive either EMDR therapy or conventional therapy provided by the center, with an equal chance of receiving either treatment (like tossing a coin). In all cases, participants will attend one session per week lasting between 60 and 90 min. Depending on the complexity of each case, the therapies range from 40 to 63 weeks in duration, including any evaluations. A screening and a follow-up evaluation will take place two and four months after the end of therapy.

What are the possible benefits and risks of participating?
It is possible that after therapy participates will be able to feel better personally and will improve their family, friendship, or work relationships. These positive effects are very likely to be permanent after therapy is completed. In addition, this study benefits the mental health of people and communities currently affected by events such as disasters, unemployment, abuse, and pandemics.

Although all procedures are painless and do not cause physical harm, the evaluations and therapies address issues related to difficult experiences. Therefore, it could be that whoever participates may feel bad. In the event that discomfort prevents further participation, the procedure can be paused or suspended. In addition, participants may request help from the

research team if they need it, up to six months after participation. Information is also provided to contact the most appropriate health service in case a referral is required. In the event of an emergency situation (eg. suicide risk), the center also has protocols for referral.

The funding for this study ensures that the participant does not have to pay for any of the project procedures.

Where is the study run from?
The study is managed by the Laboratory of Methodology for Behavioral and Neurosciences team, University of Talca (Chile) in collaboration with the Center of Applied Psychology, University of Talca

When is the study starting and how long is it expected to run for?
From May 2021 to June 2024

Who is funding the study?
The Chilean Scientific and Technological Development Fund (FONDECYT-Chile) (Chile)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
1190578

Protocol serial number
FONDECYT-Chile 1190578

Study information

Scientific Title
Adult patients from a health center specialized in the treatment of psychological trauma; eye movement desensitization and reprocessing therapy or EMDR; conventional therapy given by the center; electroencephalographic or EEG response, symptoms of post-traumatic stress or PTSD, complex PTSD or CPTSD, borderline personality disorder or BPD, and post-traumatic growth or PTG (TEEPCBG)

Acronym
TEEPCBG

Study objectives
Without effective therapies, pre (e.g. abuse during childhood) and peri-traumatic risk factors (e. g. intensity of one traumatic event) produce an increase in the amplitude of waves (Alpha, Beta, Delta, Theta) of the cerebral cortex. This is at the base of the increase in disruptive responses (e. g. post-traumatic stress disorder) and the slight increase in healthy responses (e.g. post-traumatic growth). However, effective therapies like EMDR similarly mitigate the effect of these factors, decreasing the amplitude of these waves. This would decrease disruptive responses and increase healthy ones.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/06/2019, Scientific Ethics Committee of the University of Talca (Lircay Av. n/n, Casilla 747, Talca, Chile; +56712203065; cec@utalca.cl), ref: 10-2019

Primary study design
Interventional

Study design
Single-center interventional single-blinded randomized controlled trial

Study type(s)
Treatment, Efficacy

Health condition(s) or problem(s) studied
Disruptive and healthy responses related to psychological trauma: post-traumatic stress disorder (PTSD), complex post-traumatic stress disorder (cPTSD), borderline personality disorder (BPD), post-traumatic growth (PTG)

Interventions
Patients from the Center for Applied Psychology of the University of Talca will be randomly included in one of the 2 clinical trial groups:
1. EMDR treatment
2. Conventional center treatment
Both groups will be matched according to risk factors (sex, educational level, belonging to minorities, psychiatric comorbidities, and history of child abuse). To control the effect of the therapist, each one will deliver the two psychotherapies according to random assignment.

The selection will be made by the responsible researcher for the project, using the Excel formula "RANDBETWEEN(1;2)". The responsible researcher will also be the one who matches both groups of therapies according to risk factors (sex, educational level, belonging to minorities, psychiatric comorbidities, and history of child abuse). Subsequently, the result of the draw will be communicated to each therapist. Each therapist is expected to see at least 20 patients a year, 60 by the end of the clinical trial. At least three therapists will work on the project.

Before starting, each patient will sign the informed consent approved by the Scientific Ethics Committee of the University of Talca, explaining the general conditions of their participation (e. g. voluntary, anonymity, absence of costs, evaluations).

Treatment sessions will begin once per week, with each session lasting between 60 and 90 min, depending on the complexity of the case and the stage at which treatment is. Treatment will begin with 3 sessions of therapeutic framing and move on to 4 sessions of baseline evaluation, then the treatment itself will begin, and will last a maximum of 44 (EMDR) to 55 (conventional therapy) sessions.

At the start of the study, in the middle of treatment, at the end of treatment, and 4 months after the end of treatment, evaluation sessions will be carried out. All evaluations include a clinical interview, application of EEG procedure and test to evaluate PTG, PTSD, CPTSD and BPD. Where not able to perform face-to-face procedures due to health security issues (e.g. COVID-19), the online versions of therapies will be applied. The evaluations can also be performed online, except for the EEG procedure, which is face-to-face and would not be performed.

Intervention Type
Behavioural

Primary outcome(s)
1. Electrical activity of the brain measured using the Biosemi 64-channel electroencephalography (EEG) system at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
2. Post-traumatic Stress Disorder (PTSD) measured using the Post-traumatic Stress Disorder Checklist-Civilian version (PCL-C) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
3. Complex Post-traumatic Stress Disorder (cPTSD) measured using the International Trauma Questionnaire (ITQ) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
4. Borderline Personality Disorder (BPD) measured using the Personality Assessment Inventory-Borderline Scale (PAI-BOR) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
5. Post-traumatic growth measured using the Post-Traumatic Growth Inventory (PTGI) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment

Key secondary outcome(s)
1. Disturbance measured using the Subjective Units of Disturbance Scale (SUD) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
2. Dissociation measured using the Dissociation Experiences Scale (DES) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment
3. Traumatic events measured using the Life Events Checklist for DSM-5 (LEC-5) at baseline, in

the middle of treatment, at the end of treatment, and 4 months after treatment
4. Depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, in the middle of treatment, at the end of treatment, and 4 months after treatment

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 05/04/2024:
1. Aged between 18 and 59 years
2. Exposed to at least one traumatic event

Previous participant inclusion criteria:
1. Aged between 18 and 70 years
2. Exposed to at least one traumatic event

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
59 Years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Recent (within the previous 6 months) suicide attempt
2. Severe psychiatric comorbidities (such as schizophrenia)
3. Requiring hospitalization
4. Problem drug or alcohol use
5. High dissociation

Date of first enrolment
02/05/2021

Date of final enrolment

30/05/2023

Locations

Countries of recruitment
Chile

Study participating centre
Center of Applied Psychology University of Talca
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Study participating centre
Laboratory of Methodology, Behavior and Neuroscience, University of Talca
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Sponsor information

Organisation
University of Talca

ROR
https://ror.org/01s4gpq44

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

Alternative Name(s)
National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical considerations given by the Scientific Ethics Committee of the University of Talca.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/04/2025	06/06/2025	Yes	No