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Can Eye Movement Desensitization Reprocessing (EMDR) improve the treatment of depression, compared to Cognitive Behavioural Therapy (CBT)? The European Depression EMDR Network study [EDEN]

Submission date
28/12/2011

Recruitment status
No longer recruiting

Registration date
19/01/2012

Overall study status
Completed

Last Edited
07/03/2018

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 many cases, the treatment of patients with recurrent depressive disorders is not very successful. Persisting symptoms, high relapses and suicides are important problems in the treatment of these disorders. The current methods used to treat depression are medication and /or psychotherapeutic approaches like Cognitive Behavioural Therapy (CBT). New research shows a clear relationship between depressive disorders, stressful life events and psychologically traumatic events. There are proven psychotherapy methods to treat such psychological trauma successfully. One of the most successful methods is EMDR (Eye Movement Desensitization and Reprocessing). There has not been a lot of research on trauma-adapted approaches. This study has two aims: to check whether patients with recurrent depressive disorders benefit from a trauma-adapted psychotherapeutic intervention (by using EMDR) compared to CBT (in addition to standard clinical management and medication) and medication only; and to check if the relapse rate of patients with depressive disorders can be reduced by using EMDR.

Who can participate?
You can participate if you are 18-65 years old and suffer from a present depression and have had a depressive episode before (recurrent depression).

What does the study involve?
Each center will randomly allocate patients with recurrent depressive disorders into two or three treatment groups (depending on the availability of CBT therapists in the center):
1. The pharmacological treatment currently followed in this center (Treatment As Usual, TAU)
2. Treatment with EMDR, in addition to the pharmacological treatment currently followed in this

center
3. Treatment with CBT, in addition to the pharmacological treatment currently followed by the patients already

What are the possible benefits and risks of participating?
The present study does not include the administration of new treatments. Patients will only use proven treatments. The risks are expected to be comparable to risks typically associated with the medication used and psychotherapeutic sessions (temporary increase of the level of distress, increase of physical arousal).

Where is the study run from?
From six centres in four European countries (Germany, Italy, Spain and Turkey)

When is the study starting and how long is it expected to run for?
January 2012 to December 2013

Who is funding the study?
The study is funded by the individual six centres, with some support some from the national EMDR organisations (EMDR Germany, EMDR Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Role of adjunctive Eye Movement Desensitization Reprocessing and Cognitive Behavioural Therapy (CBT) in reducing depressive symptoms in patients with recurrent depression: a randomized controlled clinical trial

Acronym
EDEN

Study objectives
The present study will target patients with recurrent depression. Persisting symptoms, high relapses and suicides are important challenges in the treatment of this disorder. It requires a large amount of money to be treated and causes a heavy social burden. Despite the large economical investments, the treatment of patients with recurrent depression is currently only moderately successful.

Hypotheses:
1. There is a significant connection between psychological traumas and depressive disorders. Often a phase of depression is initiated by a stressful event. If those traumatic memories in depressive patients are treated, the relapse rate could be reduced too.
2. Traumatized patients with recurrent depressive disorders do not respond well to pharmacological treatment alone. A trauma-adapted treatment (i.e. EMDR) may improve the treatment of depressive patients.
3. As the EMDR method accelerates and facilitates the information processing, the processing of traumatic memories may improve general health and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Hospital San Luigi Gonzaga Ethics Committee, Orbassano, Italy, 06/05/2011, ref: 6 /2011

Study design
Multi-center randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Recurrent depression

Interventions
The study is designed as a multi-center randomized controlled clinical trial. It will involve six Centers in four European Countries, and it will aim at recruiting a total of N = 500 participants.

Each Center will randomize patients with recurrent depressive disorders in two or three treatment conditions (depending on the availability of CBT therapists in the Center). The possible three treatment conditions are as follows:

Treatment as usual (TAU): The patients included in this control arm will get the pharmacological treatment and the clinical management typically provided to them by the center. There will be no indication of which pharmacological treatments should be administered or not, as recent scientific research has demonstrated the relative equivalence of different antidepressant treatments on clinical grounds. Obviously, the treatments administered should be recognized as indicated for recurrent depression, and their clinical efficacy should have been previously demonstrated via a series of rigorous clinical trials.

TAU+EMDR: A defined number of adjunctive EMDR sessions, in addition to the TAU previously described. The number of planned EMDR sessions will be 12 ± 6.

TAU+CBT: A define number of adjunctive CBT sessions, in addition to the TAU previously described. The average number of planned CBT sessions will be 15.

The clinical management sessions will be 7 for each patient, independently from the treatment arm the patient has been assigned to. If strictly necessary, additional sessions will be planned but this should be considered as an exception. The first session will be the one in which the patient is definitely included in the study, if he/she satisfies all of the criteria for the study, and accepts to participate. The second session will be scheduled after two weeks, in order to verify patients adherence to the study, and to plan the beginning of the EMDR (and CBT) sessions, if scheduled. Then, the other five sessions will be scheduled on a monthly basis. This intervention will last approximately 6 months. Follow-ups will be scheduled at 1, 2 and 5 years.

The number of EMDR sessions will be allowed to vary between 6 and 18 (12 ± 6). This relatively flexible range of sessions has been chosen with a twofold aim:
1. To avoid a large disparity of treatment amongst patients (i.e. within Center variation) and amongst Centers (i.e. between Centers variation), as each therapist will not be allowed to schedule a number of sessions < 6, or > 18; 2. To allow the EMDR therapist to schedule a number of sessions appropriate for the patient at hand within the defined range, as each patient may require a different number of sessions.

The session will be scheduled on a weekly basis. The duration of this intervention will depend mainly on the number of scheduled sessions for the patient. To summarize, it will vary between two and four months. Follow-ups will be scheduled at 1, 2 and 5 years.

CBT will follow validated protocols for the treatment of depression. In order to maintain a high degree of comparison between EMDR and CBT treatments, the number of CBT sessions to be scheduled for each patient will be allowed to vary between 10 and 20. The session will be

scheduled on a weekly basis. The duration of this intervention will depend mainly on the number of scheduled sessions for the patient. To summarize, it will vary between three and five months. Follow-ups will be scheduled at 1, 2 and 5 years.

Clinical tools that will be administered to each patient:

The following tools will be administered only at the beginning of the study:
1. DES (exclusion of a dissociative disorder)
2. TAQ (assessment instrument for traumatic events in life)

The following tools will be administered at the beginning of the study, at the end of the clinical interventions scheduled, and at follow-ups:
1. The Global Assessment of Functioning Scale (Axis V in the DSM IV) Last year, and currently
2. MINI-Plus Interview
3. Becks Anxiety Inventory
4. IES-R (impact of event scale for PTSD symptoms);
5. WHOQoL-Bref (Quality of life questionnaire).

The Beck's Depression Inventory-II (BDI-II) will be administered regularly (i.e. at the beginning of each clinical management session)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Response rates in the different treatment arms including the number of complete remissions, as measured by a BDI-II score below 12 and a MINI-Plus Interview negative regarding depression
2. Time frame of the response
3. Relapse rate at the end of the study, after 1 year, after 2 years, and after 5 years, as measured by a BDI-II above 12 and/or a MINI-Plus positive for a depressive episode

Secondary outcome measures
Quality of life, measured using the WHOQoL-Brief at baseline, at the end of the treatment, and at the scheduled follow ups

Overall study start date
01/01/2012

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Between the ages of 18 and 65 years
2. A score of at least 12 on the Beck's Depression Inventory - II (BDI-II)
3. The co-morbidity can be post-traumatic stress disorder (PTSD), adjustment disorders or other (or no) co-morbidity

4. The patient should be able and willing to discuss possible stressful life events and/or negative belief systems that support the depression

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The expected total recruitment of patients is N = 500

Key exclusion criteria
1. A history of psychotic symptoms or schizophrenia
2. Bipolar disorder, or dementia
3. Cluster A and B severe personality disorders
4. Dissociative disorders (DES > 25%)
5. Any substance-related abuse or dependence disorder (except those involving nicotine) within six months before the study began
6. A serious, unstable medical condition
7. Current pregnancy
8. Parallel legal processes or applications for pension or social security

Date of first enrolment
01/01/2012

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
Germany

Italy

Spain

Türkiye

Study participating centre
EMDR Institute
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Sponsor information

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Sponsor type
Research organisation

Website
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Funder(s)

Funder type
Research organisation

Funder Name
European Depression EMDR Network (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/02/2018		Yes	No