Comparing EMDR with CBT for the treatment of anorexia nervosa

Submission date	Recruitment status	Prospectively registered
13/10/2019	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/10/2019	Completed	Results
Last Edited	Condition category	Individual participant data
14/02/2025	Mental and Behavioural Disorders	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Anorexia nervosa (AN) is a severe mental disorder in which a person fears gaining weight or becoming fat, even though they might be very underweight. A person with AN may reduce their food intake, increase exercise and use laxatives or vomiting in order to control their weight and size. Some people with AN and other eating disorders have experienced trauma in their childhood and it is thought that the disorder may be a way of coping with negative emotions and experiences.

Eye movement desensitization and reprocessing (EMDR) is a type of talking therapy in which a person recalls memories of traumatic events and is guided by the therapist to move their eyes or hands in a certain way. This is thought to help the mind process the experience and make it less troubling. EMDR has been used in people with post-traumatic stress disorder (PTSD), but little is known about whether it might help people with AN.

This study aims to compare EMDR with cognitive behavioural therapy (CBT, another widely used talking therapy) in people with AN.

Who can participate?

Girls and women aged 15-25 years with AN

What does the study involve?

The participants will be randomly allocated to receive 16 sessions of EMDR or CBT. They will be followed up after the last treatment session and 6 months after that.

What are the possible benefits and risks of participating?

There are no potential risks envisaged other than the possibility of a worsening of the participants' condition. Any health conditions or side effects will be managed according to the best clinical practice in the center. Participants will be evaluated on a case—by—case basis by the researchers to decide whether they should continue participating in the study.

Where is the study run from?
Presidio San Paolo Psychiatric Hospital (Italy)

When is the study starting and how long is it expected to run for? May 2017 to December 2024

Who is funding the study? Italian EMDR Association (Italy)

Who is the main contact?

Dr Sara Bertelli, sara.bertelli@asst-santipaolocarlo.it

Contact information

Type(s)

Scientific

Contact name

Dr Sara Bertelli

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

0000306

Study information

Scientific Title

Eye Movement Desensitization and Reprocessing (EMDR) versus Cognitive-Behavioral Therapy (CBT) in the treatment of anorexia nervosa: a randomized clinical trial

Acronym

EMDR-DCA

Study objectives

This study aims to investigate the differences in clinical and neurophysiological outcome in anorexia nervosa after treatment with CBT or EMDR therapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/03/2018, Comitato Etico Milano Area 1, ASST Santi Paolo e Carlo (74 via GB Grassi, 20157 Milan, Italy; +39 02 8184 4118; comitatoetico.hsp@asst-santipaolocarlo.it), ref: 0000306

Study design

Single-center interventional randomized longitudinal trial study

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Anorexia nervosa

Interventions

Participants will receive 16 Cognitive-Behavioral Therapy (CBT) or Eye Movement Desensitization and Reprocessing (EMDR) sessions with a licensed psychotherapist in a blockrandomized order. First follow-up (T1) will be at the end of 16 sessions and second follow-up (T2) 6 months after the last session.

Adverse events (AEs) are highly underreported in psycholological RCTs. In line with recent recommendations, the investigators will report the proportion of patients who deteriorate on clinical measures in both the experimental and control groups. They will explain how AEs were defined and recorded and will try to identify AEs that are plausibly related to the intervention

Intervention Type

Behavioural

Primary outcome measure

Eating disorder severity measured using the global score of the Eating Disorder Examination (EDE) questionnaire from T0 (baseline) to T1 (after 16 therapy sessions)

Secondary outcome measures

- 1. Eating Disorder Severity measured using the global score of the Eating Disorder Examination (EDE) questionnaire from T1 (after 16 therapy sessions) to T2 (6 months after the last session)
- 2. Emotional regulation ability assessed using the Difficulties in Emotion Regulation Scale (DERS) at baseline, T1 and T2
- 3. Psychosocial impairment severity assessed using the Clinical Impairment Assessment (CIA) questionnaire at baseline, T1 and T2
- 4. Attitudes towards the body assessed using the Body Attitudes Test (BAT) at baseline, T1 and T2
- 5. Dissociative symptoms assessed using the Dissociative Experiences Scale (DES) at baseline, T1 and T2
- 6. Attachment assessed using the Adult Attachment Interview (AAI) at baseline, T1 and T2
- 7. Body mass index (BMI) assessed by measuring weight and height at baseline, T1 and T2
- 8. Brain activity measured using high-density electroencephalography (EEG) using 64 scalp electrodes during the AAI at baseline and T1

Overall study start date

01/05/2017

Completion date

15/12/2024

Eligibility

Key inclusion criteria

- 1. Females aged 15-25 years
- 2. Newly diagnosed with anorexia nervosa using DSM-V criteria

Participant type(s)

Patient

Age group

Mixed

Lower age limit

15 Years

Upper age limit

25 Years

Sex

Female

Target number of participants

50

Total final enrolment

53

Key exclusion criteria

- 1. Inability to speak or read Italian language
- 2. Any general medical condition interfering with eating habits, including metabolic disorders
- 3. Perinatal trauma or severe neurological disorder
- 4. Any severe psychiatric comorbidity (excluding personality disorders)
- 5. Psychotherapy of any kind in the previous year
- 6. EMDR or CBT psychotherapy in the medical history

Date of first enrolment

14/03/2018

Date of final enrolment

15/05/2024

Locations

Countries of recruitment

Italy

Study participating centre

Department of Mental Health and Addiction, San Paolo University Hospital, ASST Santi Paolo e Carlo

via Antonio di Rudinì 8 Milano Italy 20142

Sponsor information

Organisation

ASST Santi Paolo e Carlo

Sponsor details

Ospedale San Paolo U.O. Psichiatria 52 Via A. di Rudinì, 8 Milan Italy 20142 +39 0281844732 ambulatorio.dca.hsp@asst-santipaolocarlo.it

Sponsor type

Hospital/treatment centre

Website

http://www.asst-santipaolocarlo.it/

ROR

https://ror.org/0026m8b31

Funder(s)

Funder type

Other

Funder Name

Associazione per l'EMDR in Italia [Italian EMDR Association]

Results and Publications

Publication and dissemination plan

Publication will include results on clinical outcome and EEG coherence before and after treatment. Dissemination of the trial also will include presentations and talks in international conferences.

Intention to publish date

15/09/2025

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Other