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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
U.O. di Psichiatria Presidio San Paolo
via Antonio di Rudinì 8,
Milan
Italy
20142
+39 0239043518
sara.bertelli@asst-santipaolocarlo.it

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 block-randomized 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