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Adaptation, application, and evaluation of an intervention program for relatives and adult patients with anorexia nervosa

Submission date
12/01/2024

Recruitment status
No longer recruiting

Registration date
21/03/2024

Overall study status
Ongoing

Last Edited
20/01/2025

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Eating disorders are highly complex multicausal mental health illnesses that present serious medical complications and predominantly affect adolescents and young women. These disorders are characterized by severe symptoms, a high degree of comorbidity, and mortality. When the disorder worsens, either due to biological factors posing a risk of serious complications and/or the presence of depressive symptoms with a risk of self-harm, and/or the individual is incapable, due to their psychopathology, of adhering to outpatient program guidelines, patients need to be hospitalized for treatment. During hospital treatment, weight and nutritional status are restored or normalized, physical complications are addressed, education on healthy eating patterns and nutrition is provided, and inappropriate thoughts, feelings, and behaviours related to weight, body image, and food are modified and improved.

However, one of the significant challenges of inpatient treatment for these disorders is the difficulty these patients face in applying and maintaining the learned guidelines in their everyday lives post-hospitalization. As a result, there is a high rate of relapse and readmission, linked to treatment resistance, low motivation for change, severe pre-treatment caloric restriction, low body mass index, and increased work and social stress. The high relapse rates highlight the need to optimize patient treatments after hospitalizations through support in day hospital care and transition to the community through specialized psychological interventions.

To address this, the team led by Professor Janet Treasure at King's College London developed the ECHOMANTRA intervention program, aimed at facilitating the transition from inpatient treatment to daily life in the community. This program is based on scientific evidence indicating that interventions targeting not only these patients but also their caregivers improve patient health outcomes, as involving the family in the treatment of eating disorders is a key strategy for recovery. ECHOMANTRA consists of an intervention program for family caregivers (ECHO; Experienced Carers Helping Others) and another for patients (MANTRA). This study aims to assess the effectiveness of the combined intervention with treatment as usual (ECHOMANTRA + TAU) compared to TAU alone in adult women with anorexia nervosa

Who can participate?
Adult anorexia nervosa patients aged 18 to 40 years old with a BMI ≤18.5 who are receiving treatment in a specialized eating disorder unit and their carers

What does the study involve?
Participants will be randomly allocated to the control or experimental group. In the experimental group, the adaptation of the ECHOMANTRA programme will be implemented. This programme involves a skills-sharing intervention for patients with eating disorders and their carers. Participants allocated to the control group will follow the treatment provided in the specialized eating disorder unit where they are treated (treatment as usual).

What are the possible benefits and risks of participating?
There should be benefits in the transition of these patients from inpatient to daily life, dadpositive cognitive and behavioural changes and strengthened relationships with their family and social groups. There will be no risk.

Where is the study run from?
The study has been set up by the University of Miguel Hernandez (Elche) in collaboration with several units for the treatment of eating disorders from different hospitals: Eating Disorders Unit of San Juan de Alicante University Hospital, La Fe University Hospital in Valencia, Ciudad Real University Hospital, Castellón University Hospital, La Ribera University Hospital, and Igualada University Hospital

When is the study starting and how long is it expected to run for?
March 2023 to February 2027

Who is funding the study?
State Research Agency (Spain)

Who is the main contact?
Dr Yolanda Quiles Marcos
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
PID2022-139623OB-I00

Study information

Scientific Title
Adaptation, application, and evaluation of an intervention program for relatives and adult patients with anorexia nervosa: The Echomantra. A randomized controlled trial

Acronym
ECHOMANTRA

Study objectives
This study aims to evaluate the efficacy of an adaptation of a novel intervention for adult anorexia nervosa patients and their carers as an add-on to treatment-as-usual.

Hypothesis:
1. Patients from the experimental group (Treatment As Usual + ECHOMANTRA) will show significantly greater improvements in health outcomes (body mass index, symptoms, emotional state, psychosocial adjustment, perfectionism, motivation to change), and other efficacy indicators (rate of treatment dropout and readmission) in comparison to patients from the control group.
2. The efficacy of the combined intervention (TAU+ ECHOMANTRA) will be stable in the short (6 months) and middle term (12 months).
3. Family members from the experimental group will present a better emotional state and lower symptom accommodation, expressed emotion, and symptom impact in comparison to family members from the control group.
4. Family members from the experimental group will have more ED carer skills in comparison to family members from the control group.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/12/2023, Comité Ético De Investigación Con Medicamentos Del Departamento De Salud De Alicante – Hospital General (C/Pintor Baeza, 12, Alicante, 03010, Spain; +34 965913921; ceim_hgua@gva.es), ref: 2023-145

Study design

Multicentre pilot randomized controlled superiority study with two parallel groups

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Adult anorexia nervosa (AN) patients will be recruited from different specialist inpatient/day-patient eating disorder units. This study will involve adult girls who have received an AN diagnosis according to DSM-5 criteria. Patients will be asked to nominate a carer and the researcher will invite that carer to participate in the trial.

Once the informed consent has been signed and the questionnaires completed, the patients and their caregivers will be randomized as a dyad to receive either the ECHOMANTRA intervention as an add-on to treatment-as-usual (TAU) or TAU alone. Randomization is performed using a computer-generated random sequence. A complete randomization procedure macro will be applied, saving the 'seed' (SEED = 13012021) for reproducing the exact selection. Randomization will be facilitated by S. L., a colleague from the Department of Behavioral Sciences and Health, who will not be involved in this study but is an expert in these procedures and has collaborated with the team on previous projects. Once the allocation is assigned, no changes can be made.

In the experimental group, the adaptation of the Echomantra programme, developed by Professor Janet Treasure and her research team (Cardi et al., 2017), will be implemented. This programme involves a skills-sharing intervention for patients with eating disorders and their carers. The ECHOMANTRA-guided skills-sharing intervention includes materials and eight online sessions (one per week) for carers and patients.

Participants assigned to the control group will follow the treatment as usual (TAU) provided in the eating disorder unit where they are receiving their treatment.

A repeated measures analysis will be conducted at 3, 6, and 12 months following randomisation.

Intervention Type
Behavioural

Primary outcome(s)
1. Psychological well-being measured using the Depression, Anxiety and Stress Scale (DASS-21) at baseline, 3, 6, and 9 months
2. Eating disorders symptoms measured using the Eating Disorder Examination Questionnaire (EDE-Q) at baseline, 3, 6, and 12 months

Key secondary outcome(s))
1. Body mass index measured using weight and height at baseline, 3, 6, and 12 months
2. Obsessive-compulsive symptoms measured using the Obsessive-Compulsive Inventory-Revised (OCI-R) at baseline, 3, 6, and 12 months
3. Motivation to change measured using a Visual analogue scale that assesses confidence and

importance in changing symptoms of ED at baseline, 3, 6, and 12 months
5. Psychosocial adjustment measured using the Eating Disorders Quality of Life (EDQL) at baseline, 3, 6, and 12 months
6. Number of days in hospital or day centre measured using a register at baseline, 3, 6, and 12 months

Completion date
02/02/2027

Eligibility

Key inclusion criteria
1. Adult women with a primary diagnosis of AN according to DSM-V criteria
2. BMI ≤18.5
3. Receiving care in a specialized eating disorder unit (24-hour inpatient unit, day hospital, or outpatient clinics)
4. With a willing family member to participate
5. With the ability to handle an electronic device (e.g., computer, laptop, or tablet) and internet to access online sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Key exclusion criteria
1. Severe psychiatric or medical comorbidity preventing program completion
2. Inadequate understanding and proficiency in the Spanish language
3. Prior participation in groups, programs, or therapies utilizing MANTRA

Date of first enrolment
01/03/2023

Date of final enrolment
02/02/2026

Locations

Countries of recruitment
Spain

Study participating centre
University Miguel Hernandez. Behavioral Sciences and Health Department
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Sponsor information

Organisation
Agencia Estatal de Investigación

ROR
https://ror.org/003x0zc53

Funder(s)

Funder type
Government

Funder Name
Agencia Estatal de Investigación

Alternative Name(s)
Spanish State Research Agency, Spanish Agencia Estatal de Investigación, AEI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

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 participants of this research having given their consent for their data to be used only for the purposes of this research

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		13/01/2025	11/06/2024	Yes	No
Participant information sheet			16/01/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes