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Adaptation and implementation of an intervention programme on Spanish carers and adolescent patients with an eating disorder

Submission date
23/04/2021

Recruitment status
No longer recruiting

Registration date
18/05/2021

Overall study status
Completed

Last Edited
21/12/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
One of the major problems with inpatient treatment of adolescent girls with an eating disorder (ED) is that the guidelines learned during their hospital stay are not easily applied or maintained in their daily lives, and this has been related to high rates of relapse and readmission. Interventions that may optimise the outcome during and following inpatient or day-patient treatment are needed, and to this end, the ECHOMANTRA programme has been developed. The aim of this study is to evaluate the effectiveness of an adaptation of a novel intervention for eating disorder patients and their carers (ECHOMANTRA) as an add-on to treatment-as-usual.

Who can participate?
Adolescent patients diagnosed with an eating disorder receiving treatment in a specialist inpatient/day-patient 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 to facilitate the transition from hospital/daycare center back into the community. Participants allocated to the control group will follow the treatment provided in the hospital /day center where they are treated (treatment as usual).

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

Where is the study run from?
The study has been set up by the Universities of Miguel Hernandez (Elche) in collaboration with the Eating Disorders Unit of the San Juan of Alicante Hospital, CREA, and ADANER (Spain)

When is the study starting and how long is it expected to run for?
February 2020 to November 2022

Who is funding the study?
Alicia Koplowitz Foundation (Spain)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
ID:2020/49555

Study information

Scientific Title
Adaptation and implementation of an intervention programme on Spanish carers and adolescent patients with an eating disorder: a randomised controlled trial

Study objectives

The aim of this study is to evaluate the efficacy of an adaptation of a novel intervention for eating disorders 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 (9 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
Old ethics approval format

Ethics approval(s)
Approved 17/11/2020, Ethics Committee of the University Miguel Hernandez (Comité De Ética E Integridad en La Investigación, Vicerrectorado De Investigación, Universidad Miguel Hernández De Elche, Avda. de la Universidad s/n, C. P. 03202 Elche (Alicante), Spain; +34 (0)965222687; oir@umh.es), ref: 2020/49555

Study design
Multicentre pilot randomized controlled blind superiority study with two parallel groups

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Eating disorders

Interventions
Patients will be recruited from three different specialist inpatient/day-patient eating disorder units. This study will involve adolescent girls who have received an eating disorder 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.

After screening and consent, patients and their carers will be randomised as a dyad using a randomised computer-generated sequence. Eating disorder patients and their carers will be randomised to receive either the ECHOMANTRA intervention as an add-on to treatment-as-usual (TAU) or TAU alone.

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 to facilitate the transition from hospital/day care centre back into the community. 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 hospital center where they are receiving their treatment.

A repeated measures analysis will be conducted at 3, 6, and 9 months following randomisation.

Intervention Type
Behavioural

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

Key secondary outcome(s))
1. Body mass index measured using weight and height at baseline, 3, 6, and 9 months
2. Obsessive-compulsive symptoms measured using Obsessive-Compulsive Inventory-Revised (OCI-R) at baseline, 3, 6, and 9 months
3. Perfectionism measured using Child and Adolescent Perfectionism Scale (CAPS) at baseline, 3, 6, and 9 months
4. Motivation to change measured using a Visual analogue scale that assesses confidence and importance in changing symptoms of ED at baseline, 3, 6, and 9 months
5. Psychosocial adjustment measured using Eating Disorders Quality of Life (EDQL) at baseline, 3, 6, and 9 months
6. Number of days in hospital or day centre measured using a register at baseline, 3, 6, and 9 months

Completion date
01/11/2022

Eligibility

Key inclusion criteria
1. Adolescent girls who have received an eating disorder diagnosis according to DSM-5 criteria (American Psychiatric Association, 2013), including diagnoses of anorexia nervosa, bulimia nervosa, and other specified or unspecified eating disorders
2. Age between 12 and 19 years
3. No psychiatric comorbidity
4. Receiving treatment for ED in a specialist inpatient/day-patient ED unit
5. A family member willing to participate in the study
6. Ability to manage an electronic device (e.g. mobile phone, computer, laptop, tablet) and the Internet in order to access the online sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
1. Suffer from a severe mental or physical illness that needs priority treatment (for example psychosis, acute suicidality, substance abuse)

Date of first enrolment
01/02/2021

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
Spain

Study participating centre
University Miguel Hernández
Behavioral Sciences and Health Department
Avda. de la Universidad s/n
Alicante
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Sponsor information

Organisation
Fundación Alicia Koplowitz

ROR
https://ror.org/036jhs482

Funder(s)

Funder type

Charity

Funder Name
Fundación Alicia Koplowitz

Alternative Name(s)
Alicia Koplowitz Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
Results article		15/05/2024	25/06/2024	Yes	No
Protocol article		22/10/2021	21/12/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes