

STUDY PROTOCOL

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# Efficacy of the ECHOMANTRA online intervention to support recovery from anorexia nervosa in adult patients: study protocol of a randomized controlled multi-center trial

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## Abstract

**Background** Poor quality of life in adults with anorexia nervosa (AN) and persistent high rates of readmission highlight the necessity of developing interventions to optimize treatment outcomes. ECHOMANTRA is a novel online intervention based on interventions for carers (Experienced Carers Helping Others, ECHO) and patients (Maudsley Model of Anorexia Nervosa Treatment for Adults, MANTRA) with anorexia nervosa. The objective of this paper is to describe the study protocol of a randomized control trial (RCT) aimed at evaluating the efficacy of an adaptation of the ECHOMANTRA for adults AN inpatients and outpatients, and their carers, to be implemented as an add-on to treatment-as-usual (TAU).

**Methods** In a multi-center pilot randomized controlled trial (RCT), 148 adult AN patients, and their carers, will be randomized to receive treatment as usual (TAU) or TAU plus ECHOMANTRA. Assessments will take place at baseline (T0), post-intervention (2-month) (T1), 6-month follow-up (T2), and 12-month follow-up (T3). Primary outcomes will be eating disorder psychopathology and psychological well-being. For carers, outcome variables will include psychological well-being, accommodation and enabling behaviors, expressed emotion, illness burden, quality of life and care skills.

**Discussion** This study will provide evidence of the efficacy of this novel, online and protocolized intervention in facilitating the recovery of these patients.

**Trial registration** ISRCTN registry (Identifier: 80253157 <https://doi.org/10.1186/ISRCTN80253157>).

**Keywords** RCT, Adult, Anorexia nervosa, Treatment, ECHO, MANTRA

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## Background

Anorexia nervosa (AN) is marked by restrictive eating and significant weight loss. Individuals with AN have an intense fear of gaining weight or becoming fat and may engage in behaviors that prevent weight gain [3]. Anorexia nervosa (AN) is a disabling, life-threatening, and costly mental disorder that severely affects physical health, disrupts psychosocial functioning, and is commonly associated with psychiatric comorbidities [54]. A recent review revealed that prevalent psychiatric comorbidities include anxiety (with rates up to 62%), mood disorders (with rates up to 54%), and substance use disorders along with post-traumatic stress disorder, each demonstrating similar comorbidity rates of up to 27% [24]. AN has one of the highest mortality rates amongst all psychiatric illnesses [7, 35]. The main causes of death are related to specific medical conditions as well as suicide [6, 63]. Many patients with very severe AN recover from their illness, but still suffer from considerable long-term negative consequences. According to a large longitudinal study of inpatients with anorexia nervosa (N=1693) and a subsample (N=112), remission rates were 30% in the full sample after 10 years and 40% in the subsample with an extended follow-up period of 20 years [20]. Regarding relapses, a recent systematic review found a relapse frequency of 31% after treatment. The highest risk of relapse is during the first year after discharge and this risk continues for up to 2 years [10]. Given the impairment in quality of life, along with the high morbidity, relapse rates, and mortality associated with anorexia nervosa (AN), there is a critical need for the development of interventions that improve care for AN patients.

In response to this, Professor Janet Treasure and her team developed ECHOMANTRA, in their TRIANGLE study, a skill-sharing intervention for patients with AN and their carers [14]. ECHOMANTRA is based on the evidence that interventions aimed not only at patients, but also at their caregivers, can improve the health outcomes of patients. Involving the family in the treatment of eating disorders is a key strategy for recovery, as it strengthens patient social networks and breaks toxic loneliness and isolation [32, 55]. Furthermore, the inclusion of family members in treatment is recommended by clinical guidelines such as the National Institute for Health and Care Excellence [34] and the American Psychiatric Association [4], as recovery from AN can involve many years of treatment, leading to emotional, family, and/or economic strain [56]. Caregivers provide a substantial part of the care needed to overcome the disease [5].

ECHOMANTRA consists of an online intervention for family members (ECHO; Experienced Carers Helping Others; [57]) and patients (MANTRA, Maudsley

Anorexia Nervosa Treatment for Adults [47]). The patient intervention, MANTRA, is based on the Interpersonal Cognitive Maintenance Model of AN [46, 58] which identifies the key internal and interpersonal maintaining factors of the disorder. The model includes four main maintaining factors: a thinking style characterized by rigidity, attention to detail, and a fear of making mistakes, an avoidant approach to emotion processing; positive beliefs about anorexia nervosa (pro-anorexia beliefs); and the responses of close others, characterized by high expressed emotion and enabling and accommodating behaviors. MANTRA targets emotional regulation difficulties and eating behavior, with a particular emphasis on behavior change strategies.

MANTRA has shown its efficacy in the treatment of adult patients with AN [13, 22, 43–45, 52] and is recommended by the NICE guidelines [34] for these patients. The treatment consists of seven core modules delivered over 20–40 individual weekly sessions, depending on the severity of the illness. This intervention comprises a patient workbook that integrates components of cognitive behavioral therapy (e.g., a diagrammatic case formulation emphasizing maintaining factors) and writing exercises that facilitate emotion expression and regulation, drawing from the foundational concepts of James Pennebaker. The therapeutic approach of motivational interviewing is employed to enhance intrinsic motivation for change and address resistance. In the TRIANGLE study [14], MANTRA was condensed into eight online group sessions targeting motivation to change and recover, healthy food intake and nutrition; interpersonal difficulties; flexible thinking and effective emotion regulation; and the development of an identity separate from AN.

The ECHO part of intervention is based on the Model of Caregiver Coping and Stress in eating disorders [53], which includes the different aspects that influence caregiver coping and that could be problematic as sources of psychological distress. The authors differentiated between three types of factors: those associated with the disease (symptoms or lack of awareness of the disease); those related to the caregiver's emotional reactions to the disease (overprotection, symptom accommodation, expressed emotion) and those related to the social context (such as the stigma associated with the disorder). Based on this model, the ECHO part of intervention is for family members and it includes three main components: information to strengthen family members' coping in their role as caregivers; skills to reduce their expressed emotion and symptom accommodation; and skills for positive communication and behavioral change in order to support their loved ones' recovery [57]. Studies to date have shown that the ECHO programme improves

caregivers' levels of well-being, and also reduces psychological distress and expressed emotion [26, 27, 38, 40, 49]. Furthermore, patients whose caregivers participated in these groups also reduced their anxiety, depression and psychological distress scores [28, 30, 40]. Our research group implemented an intervention program based on the ECHO model for relatives of patients with eating disorders in Spain. The results demonstrated that family members who participated in the program experienced improved well-being, reduced caregiver burden, psychological distress, and expressed emotion. Additionally, only patients whose relatives participated in the program showed reductions in anxiety, depression, and psychological distress, whereas no such changes were observed in patients whose relatives were in the control group [37, 40].

In the TRIANGLE trial, the ECHOMANTRA materials consisted of an online workbook, a library of video clips, including lived experience recovery narratives and role-plays of carer skills. Both the MANTRA and ECHO parts of the intervention were delivered through eight group online sessions, which were moderated and facilitated by research assistants. We have adapted this format into our research: both MANTRA and ECHO were delivered in eight sessions, following the same contents as in the original study. However, based on the preliminary results in the UK and some recommendations [1, 2, 11], we have decided to change the delivery format. In our study, ECHOMANTRA will be delivered online via video call and the sessions will not follow a discussion group format. The qualitative results of the original study showed that the online group format was sometimes considered by AN patients as triggering and draining, and at times, they perceived a sense of competitiveness within the patient group. They also concluded that a more personalized approach is necessary, one that matches the characteristics of the participants, such as their readiness to change and the duration and severity of the illness [11]. In the present study, ECHOMANTRA will consist of eight psychoeducation and individually tailored intervention online sessions to improve participant adherence and adequately address the contents and protocol of MANTRA and ECHO. Workbooks and videos will also be used.

This adaptation of ECHOMANTRA through individual video-call sessions may be an appropriate tool, considering the recommendations of a recent systematic review that suggests adapting successful programs like ECHO to virtual environments for remote application [25]. Another difference in this research is that in the original study, the participants were only adult AN inpatients, as the main objective was to evaluate whether this programme improved the transition of these patients from

the hospital resource to their community. In our study, outpatients were included as well.

ECHOMANTRA was designed, not to replace the usual treatment provided in specialized eating disorder units, but to be used as an add on. The *objective* of this paper is to describe the study protocol of a randomized controlled trial (RCT) designed to evaluate the efficacy of a novel intervention, ECHOMANTRA, for adult anorexia nervosa (AN) patients and their carers. This intervention is adapted to be used as an add-on to treatment as usual (TAU) and will be compared to TAU alone.

### Hypotheses

- AN patients from the intervention group (TAU+ECHOMANTRA) will show significantly greater improvements in health outcomes (body mass index, eating disorder symptoms, emotional state, psychosocial adjustment, flexibility and motivation to change), and other efficacy indicators (rate of treatment dropout and readmission) in comparison to patients in the control group.
- The efficacy of the intervention group (TAU+ECHOMANTRA) will be stable in the short (6 months) and middle term (12 months).
- Family members from the intervention group will present a better psychological wellbeing and lower accommodation, expressed emotion and symptom impact in comparison to family members in the control group.
- Family members in the intervention group will have more ED carer skills in comparison to family members in the control group.

### Methods

This study is registered in the ISRCTN registry (Identifier: 80253157 <https://doi.org/10.1186/ISRCTN80253157>). The Consolidated Standards of Reporting Trials (CONSORT) statements [17] were followed in reporting this trial. Ethical approval was obtained from University Miguel Hernández Ethics Committee (ref: DCC. MQS.01.23) and all the ethics committees of the participating hospitals.

### Design and procedure

This is a randomized controlled blind superiority pilot study conducted at multiple centers, with two parallel groups. Participants will be randomly assigned to the control or experimental group using a computer-generated sequence ensuring an equal 1:1 treatment allocation ratio. At each unit, a research assistant will perform

a semi-structured interview to ensure participant eligibility.

Patients undergoing treatment for anorexia nervosa (whether as inpatients, day patients, or outpatients) who meet the study’s inclusion criteria will be invited to participate, along with a caregiver who typically supports them outside the hospital or day center and lives with them. Both patients and their caregivers, as dyads, will receive detailed information about the study and will be asked to provide informed consent before participating.

Upon submitting consent, participants will complete a baseline survey and will be randomly allocated to either: the (1) ECHOMANTRA + TAU group or to (2) TAU only group (see Fig. 1). The experimental intervention comprises guiding materials and eight online sessions (one per week) for both caregivers and patients. Treatment will last 8 weeks.

**Participants**

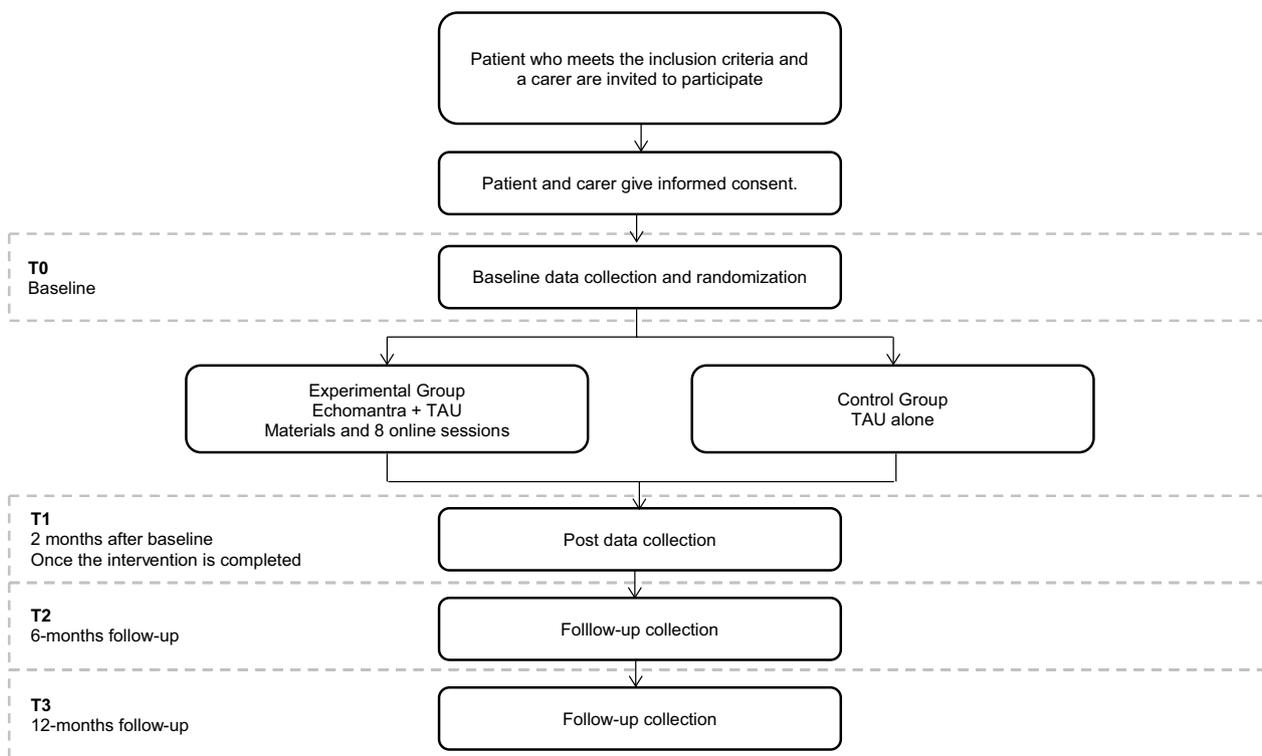
**Patients**

Patients will be enrolled from seven different specialized units for eating disorders including inpatient/day-patient/outpatient units (University and Polytechnic La Fe Hospital of Valencia, University Hospital of La Ribera (Valencia), University Hospital San Juan of Alicante, ADANER (Murcia), CREA (Alicante), University

Hospital of Igualada (Barcelona), Canary Islands University Hospital Complex, General University Hospital of Ciudad Real, and Castellón Provincial Hospital Consortium). This study will involve adult women with a primary diagnosis of AN, based on the criteria outlined in the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association [3]). Participants must meet the following inclusion criteria: (1) BMI ≤ 18.5 kg/m<sup>2</sup>, (2) receiving treatment for AN in a specialized inpatient, day-patient, or outpatient eating disorder unit, (3) with a carer disposed to participate, (4) able to use an electronic device (e.g. computer, tablet or mobile phone), (5) no severe psychiatric or medical comorbidity that would impede participation in the program, (6) fluency in Spanish, and (7) no previous participation in groups, programs, or therapies that use MANTRA.

**Carers**

Carers must meet the following inclusion criteria: (1) cohabiting with the patient, (2) no severe psychiatric or medical comorbidity that would impede participation in the program (assessed through a self-report), (3) able to use an electronic device (e.g. computer, tablet or mobile phone), (4) fluency in Spanish, and (5) no previous



**Fig. 1** Study design diagram flow

participation in groups, programs, or investigation that use ECHO programmes.

### Randomization

After screening and given consent, dyads (joint patients and their carers) will be randomized with a 1:1 ratio using a computer-generated random sequence. Allocation of participants will be performed using R version 4.3.3 (R Core Team, 20,224) with the randomizeR package. A seed value of 42 will be set prior to the randomization process to ensure reproducibility of results. Once the allocations are assigned, they cannot be altered. Dyads allocated to the TAU+ECHOMANTRA arm will access the intervention materials.

### Sample size

Regarding the estimation of sample size, a type I error of 0.05 and a contrast power of 0.80 will be taken into account. Considering an expected effect size of  $\eta^2_p = 0.10$  in the main outcome variables (DASS-21 and EDE-Q) according to previous work [26, 27, 43, 65], 52 participants will be necessary by condition ( $n = 104$ ). Assuming a 30% loss, typical of similar studies [14, 65],  $n = 148$  participants will be recruited. These analyzes have been carried out with the GPower 3.1 program.

### Interventions/treatment arms

#### *Treatment as usual*

Each center included in the study will follow their own protocol procedures for TAU. All admission units are part of the public healthcare network and adhere to the same guidelines and protocols outlined in the current clinical practice guidelines in our country [8]. A standardized comparison treatment has not been used, logistical adjustments and managing resources (including training, supervision, and ensuring quality) would be required and may not be practical. Thus, the analyses will be stratified by center and appropriately adjusted for any bias.

Inpatient care provides a tailored programme employing a multidisciplinary approach, including dietitians, psychologists, physicians, and nurses. Treatment comprises nutritional rehabilitation and education on healthy nutrition patterns, monitoring of physical risks, as well as psychological therapy to modify or improve the cognitive, attitudinal, behavioral and affective factors that maintain the illness. Once patients have reached healthy body mass indexes and show signs of stabilization, they are discharged, receiving thereafter either continued monitoring to reassure progress and facilitate transition to a day-care unit or home.

Day-care treatment entails a multidisciplinary approach that includes dietary and psychological

interventions, sessions with psychiatrists, and school education support. Patients partake in weekly individual cognitive behavioral therapy for eating disorders (CBT-ED), along with group therapy on body image, nutrition, emotional regulation, and social competences. Additionally, patients prepare their meals throughout the day. Attendance is typically required from Monday to Friday, with an average of 6 h per day. Caregivers are also invited to join a biweekly parent support group.

For outpatient care, a multidisciplinary approach is commonly used, which includes weekly or biweekly individual CBT-ED, nutritional monitoring, and psychiatric interventions when needed. Caregivers also have access to the parent support groups mentioned above.

Dyads assigned to control conditions (TAU alone group) will not have access to the ECHOMANTRA components. Once the study is concluded, they will be offered the self-help materials of the intervention.

#### *Treatment as usual plus patient and carer skill-sharing intervention (ECHOMANTRA)*

The Spanish adaptation of the ECHOMANTRA intervention will be delivered in the experimental group.

#### *Patients*

MANTRA, part of the ECHOMANTRA, draws upon the interpersonal model of AN, which addresses patients' modifiable difficulties: emotion regulation, interpersonal relationships and eating patterns. It comprises eight individual and weekly online sessions, each lasting 60 min, administered by an assistant psychologist (different from the ECHO part) which has been trained by the study's main authors.

MANTRA intervention is suited with a workbook that emphasizes specific behavioral and attitudinal change strategies. It is organized into eight chapters that complement the program's eight sessions.

Throughout the online sessions psychologists will carry out various activities derived from the MANTRA program and prompt patients to reflect on the contents proposed in each chapter of the patient workbook (see Table 1). Following the structure outlined in the workbook, the sessions will cover a variety of topics: the first and second sessions will focus on the basics of psychoeducation, including the origins and maintaining factors of the illness; the third session will address planning for transition through goal setting; the fourth session will focus on managing identity issues related to the eating disorder; the fifth, sixth, and seventh sessions will cover emotion management, exploring thinking styles, and social functioning; and the eighth session will focus on utilizing social support, implementation intentions, and relapse prevention.

**Table 1** Contents of the MANTRA program

Session	Content
1	Introduction, motivation of change assessment, and discussion on the impact of AN on the brain and the body
2	Discussion on origin and maintaining factors of the eating disorders, and behavior change strategies
3	Planning the transition: identification of behavioral goals, and discussion on goal setting strategies
4	Discussion around the relationship with AN, self-identity. Planning behavior change strategies
5	Exploration of thinking styles and its relationship with AN, and strengthening general problem solving skills
6	Discussion around the impact of the AN on emotions, and strengthening emotion management skills
7	Discussion about the impact of AN on social support, and strengthening social functioning skills
8	Discussion about social support, behavioral goals, goal setting strategies for relapse prevention and implementation intentions

See Schmidt et al. [47] for a comprehensive understanding of the intervention entailed.

**Carers**

The ECHO component of the ECHOMANTRA program consists of eight individual, weekly online sessions, each lasting 60 min, conducted by an assistant psychologist (separate from the MANTRA component) trained by the study’s lead authors. If multiple caregivers wish to participate, they are welcome to join. Both caregivers attend the sessions together, but only one completes the evaluation questionnaires, and their responses are used in the analyses.

ECHO intervention is suited with a carer workbook organized in eight chapters that complement the program’s online sessions (see Table 2). Additionally, some of the video-clips from the Digital Versatile Disc (DVD) “How to care for Someone with an Eating Disorder” are presented during the sessions. This DVD offers practical strategies aimed at equipping carers with skills and knowledge to support their loved ones and maintain their own wellbeing through the “New Maudsley Approach”. Additionally, carers will be suggested to read “Skills-based Caring for a Loved One with an Eating Disorder: The New Maudsley Method” book [59]. (Spanish version: Los trastornos de la alimentación: guía práctica para

cuidar de un ser querido, [59]. Materials are designed to develop introspection skills, foster confidence, compassion, and the willingness to take risks, and guide carers in experimenting with changes in their caregiving approach to better assist their loved one. Throughout the sessions, the psychologist will facilitate discussion on the contents and exercises presented in the workbook and additional materials.

Online sessions accompanied by the workbook will offer a comprehensive skill training programme, covering stress management, communication (using motivational interviewing techniques), accommodation and expressed emotion reduction, and strategies to enhance extinction and develop new habits at home with effective social support.

**Outcomes**

This study will evaluate outcomes at four time points: baseline (T0), post-intervention (T1), 6-month follow-up (T2), and 12-month follow-up (T3). Data will be collected using online survey software.

**Patients**

Primary outcomes for patients will be ED psychopathology and psychological well-being. Secondary outcomes will include body mass index (BMI), eating behavior,

**Table 2** Contents in the ECHO programme

Session	Content
1	Psychoeducation: better understanding of eating disorders
2	Psychoeducation: identifying strengths and resources
3	Discussion on accommodation to illness
4	Identification of emotional and behavioral responses of the carer: animal metaphor
5	Strengthening effective communication strategies: motivational interviewing
6	Strengthening effective communication strategies: compassionate communication
7	Strengthening problem resolution skills
8	Preparation for the return home

emotion regulation, psychosocial adjustment, quality of life, physical activity, cognitive flexibility, obsessive–compulsive symptomatology, motivation for change, patient’s feedback form, and hospital readmission. Outcomes and instruments are shown in Table 3.

**Clinical assessment**

The health care team at each unit will collect the following information: patient BMI up to 12 months post-randomization, diagnosis, AN age at onset, illness duration, previous admissions and treatments, comorbidity, pharmacological treatment, treatment duration in that unit, and post-discharge readmission.

**Carers**

The following outcomes will be assessed for caregivers: psychological well-being and quality of life, expressed emotion, the impact of eating disorder symptoms, coping skills, and adaptation to the illness (see Table 1). A

socio-demographic questionnaire was also administered, asking whether they had attended any support groups for relatives, along with details on the content provided and the duration of participation.

At the end of the intervention, dyads assigned to the experimental group (ECHOMANTRA + TAU) will complete a self-report ad-hoc questionnaire. This measure will assess participants’ experiences and satisfaction with the intervention, inviting feedback on perceived benefits, challenges, what they found stimulating, what they liked or disliked, the feasibility of applying the ECHOMANTRA skills in their daily lives, and suggestions for improving the intervention process.

**Blinding**

Dyads and therapists will be informed about the treatment condition given the study’s design. The researcher creating the randomization sequence will not take part in recruitment or selection of participants. The researcher

**Table 3** Variables and measurements

	Result	Instrument	References
<i>Patients</i>			
1	Body Mass Index	kg/m <sup>2</sup>	
2	ED psychopathology	Eating Disorder Examination (EDE-Q)	Fairburn and Beglin [19], Spanish Validation: Peláez-Fernández et al. [36]
3	Eating pattern	Daily food self-reporting	
4	Physical Activity	International Physical Activity Questionnaire Adaptation for Eating Disorder	Craig et al. [16], adaptation will be developed for this study
5	Psychological well-being	Depression Anxiety and Stress Scale (DASS-21)	Lovibond and Lovibond [33], SV: Bados et al. [9]
6	Psychosocial Adjustment/Quality of Life	Eating Disorders Quality of Life (EDQoL) Health Survey Short Form 12 (SF-12) Clinical Impairment Assessment (CIA 3.0)	Engel et al. [18], SV: Quiles et al. [41], Ware et al. [62], SV: Vilagut et al. [60], Bohn and Fairburn [12], SV: Martín et al. [31]
7	Obsessive Compulsive Symptoms	Obsessive Compulsive Inventory Revised (OCI-R)	Foa et al. [21], SV: González et al. [23]
8	Cognitive Flexibility	Detail and Flexibility Questionnaire (DFlex)	Roberts et al. [42]
9	Treatment Adherence	Dropout rate, number of sessions completed and task completion between sessions	
10	Motivation to change	Visual Analogue Scale that assesses confidence and importance in changing symptoms of ED	
11	Admission	Number of readmissions to hospital throughout the intervention lapse and follow-up periods. Record medical history	
12	Patient feedback form	Patients’ satisfaction and experiences in the study	
<i>Carers</i>			
1	Psychological well-being	Depression Anxiety and Stress Scale (DASS-21)	Lovibond and Lovibond [33], SV: Bados et al. [9]
2	Expressed emotion	Family Questionnaire	Wiedemann et al. [64], SV: Sepúlveda et al. [51]
3	Burden	Eating Disorder Symptom Impact Scale (EDSIS-S)	Sepúlveda et al. [49], SV: Carral-Fernández et al. [15]
4	Accommodation to illness	Accommodation to Illness Symptoms Scale (AESED)	Sepúlveda et al. [50], SV: Quiles et al. [39]
5	ED care skills	Caregiver Skills Scale	Hibbs et al. [26, 27], SV: Vintró et al. [61]
6	Quality of Life	Health Survey Short Form 12 (SF-12)	Ware et al. [62], SV: Vilagut et al. [60]
7	Carer feedback form	Carers’ satisfaction and experience in the study	

SV Spanish version

responsible for performing the pre- and post-intervention evaluation will be unaware of the experimental condition of the participating subject being evaluated; in other words, they will not have participated in the intervention phase or the assignment phase to the experimental condition. The researcher conducting the statistical analyses will also be unaware of the experimental condition of the data analyzed.

### Statistical analysis

All analyses will be conducted following the intention-to-treat principle. First, an analysis of covariance (ANCOVA) will be performed, using the type of care resource (outpatient, day hospital, or 24-h inpatient) as a control variable. Next, a repeated measures analysis of variance (ANOVA) will be used to assess the short- and medium-term efficacy of ECHOMANTRA + TAU compared to TAU alone, examining both between-group and within-group differences across multiple time points. Effect sizes will be considered for primary outcomes (e.g., eating pathology and psychological well-being in patients) and secondary quantitative outcomes (e.g., patients' BMI, physical activity, quality of life; caregivers' care skills, psychological well-being, etc.). Post-hoc analyses will be conducted to explore intra- and inter-group differences. Analyses will include stratification by the admission center. All analyses will be performed using IBM SPSS Statistics 24.0 [29].

Regarding qualitative data, including feedback forms, interviews, and participants' experiences of the program, thematic analysis will be used to identify and analyze patterns of meaning across the data.

### Discussion

The need for more advanced therapeutic strategies in the treatment of anorexia nervosa (AN) is marked by persistently high rates of readmission, relapse, and chronicity. This paper outlines the protocol for a research study designed to improve eating disorder symptoms, emotional well-being, and coping skills for addressing issues related to AN in both patients and caregivers.

Based on our current knowledge, this particular RCT of ECHOMANTRA represents the first study to implement an online psychological intervention aimed at enhancing the efficacy of standard treatment of adult patients with AN in Spain. Furthermore, the ECHOMANTRA intervention not only offers the potential to improve the well-being of individuals with AN through a combined patient-carer approach, but also contributes to the currently limited body of research on technology-based tools as a supportive element in AN treatment [14]. We have also outlined the components of the ECHOMANTRA

intervention and detailed the research methodology following the CONSORT 2010 guidelines [48].

This treatment builds on two previous psychological interventions that have already proven their effectiveness (MANTRA for patients and ECHO for caregivers). The use of ECHOMANTRA, as in previous studies [1, 2, 1114], is expected to alleviate distress and eating disorder symptoms in patients, and caregivers are expected to experience decreased levels of distress while at the same time improving their caregiving skills. Furthermore, the long-term goal of this project is to make a substantial contribution to the recovery process of these patients, increase motivation to change, adherence to treatment and minimize the risk of relapse.

The ECHOMANTRA intervention comprises eight online group sessions, which were conceptualized by Cardi et al. [14] as a novel approach. It is posited that this program is designed to be cost-effective, scalable, and potentially impactful, especially considering its positive outcomes in symptom amelioration. Notably, the online format of the program enhances its accessibility, enabling patients and their families to incorporate therapeutic practices into their daily routines, thereby promoting greater engagement in treatment. This investigation is designed as an experimental, multicenter study encompassing three service types: inpatient units, day hospitals, and outpatient consultations. This multifaceted approach permits the evaluation of the intervention's efficacy in conjunction with Treatment as Usual (TAU), considering the therapeutic context and its impact on the generalizability of the findings.

This trial has several limitations. First, one of the questionnaires used in this RCT (D-Flex) has not yet been validated in Spanish, but this will be addressed during the course of the trial. Another potential limitation is ensuring sustained engagement from both members of the dyad (the patient and the caregiver) throughout the intervention. To address this, session schedules will be personalized and collaboratively determined with each participant. Additionally, efforts will be made to maintain adherence within the control group. To support this, the self-help components of the intervention will be offered to control participants after the study concludes. Lastly, while we recognize that the number of males, transgender, and gender non-binary individuals diagnosed with anorexia nervosa (AN) has increased in recent years, this study will include only female patients. This decision is based on several factors, including the higher prevalence of AN among women, the need for sample homogeneity, and the exploratory nature of the treatment. The prevalence of AN remains significantly higher in women, and clinical manifestations and etiological factors can differ substantially between genders. To avoid confounding

variables related to gender, we have chosen to focus on women, who represent the most affected group.

In clinical studies, especially those evaluating treatment efficacy, it is important to maintain a homogeneous sample. As this study is one of the first to assess this particular treatment, we deemed it necessary to limit the sample to one gender to reduce variability. Additionally, given that this study represents an initial phase of research on an innovative treatment, ensuring its efficacy and safety within a homogeneous group is crucial before expanding its use to a more diverse population. The decision to focus on women was also influenced by practical considerations, such as patient availability and the need for a sufficient sample size to ensure the statistical power of the study. In our region, the majority of patients with AN seeking treatment are women, which made it feasible to recruit an adequate sample within a reasonable timeframe. Future studies may explore the efficacy of this intervention in male, transgender, and gender non-binary populations, as well as in other eating disorder diagnoses, and validate its effects in comparison to different control conditions.

The strengths of this study lie in its utilization of a randomized controlled trial design and the implementation of a protocolized therapist guidance system, ensuring fidelity across the intervention process. Furthermore, the trial incorporates tailored interventions for both patients and caregivers, thereby enhancing the study's methodological integrity. Finally, in accordance with the suggestions postulated by Ambawani et al. [2] this intervention will be carried out by individual online sessions that introduces an element of flexibility, addressing barriers to access and participation due to geographical constraints or personal commitments that preclude in-person attendance. The implementation of individualized session formats may significantly mitigate attrition rates among both patients and their caregivers. This assertion assumes that personalized therapeutic interventions, rather than group-based modalities, provide a tailored approach that could be more successful in addressing the individualized needs and preferences of individuals undergoing treatment for AN. Additionally, as suggested by the authors of the original study following its implementation, this research will conduct a comprehensive long-term evaluation of quality of life (QoL) for both patients and their caregivers throughout the treatment period [2]. Since QoL is a key measure for assessing the cost-effectiveness of interventions, this evaluation will provide valuable insights into the broader psychosocial benefits of specific therapeutic approaches in the treatment of anorexia nervosa (AN).

This study may have several clinical implications: Firstly, the ECHOMANTRA intervention holds promise in facilitating the recovery of adult patients with

AN, improving psychosocial functioning, emotional well-being, and reducing rates of readmission and relapse. Secondly, the implementation of a protocolized treatment in just eight sessions, using new technologies for its application, would allow broader access to a large number of patients with different geographical locations. This combination with the standard treatment offered in specialized units could lead to improved clinical outcomes. Moreover, its cost-effectiveness underscores its potential as a valuable intervention in this domain. The results of this project will provide the healthcare community with a standardized, structured resource, tailored to the Spanish population, and designed to address the needs of patients with long-term conditions, high rates of comorbidities, frequent relapses, and high care demands.

#### Abbreviations

AN	Anorexia nervosa
BMI	Body mass index
DSM	Diagnostic and statistical manual of mental disorders
ECHO	Experienced carers helping others
MANTRA	Maudsley anorexia nervosa treatment for adults
RCT	Randomized controlled trial
TAU	Treatment as usual

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#### Author contributions

YQ spearheaded the design of the trial protocol and development of intervention materials in collaboration with MCN, EL, JM, SP, KK, VC and AR. YQ, MCN, EL, JM, VC and AR co-wrote the manuscript and provided critical feedback.

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#### Availability of data and materials

No datasets were generated or analysed during the current study.

#### Declarations

##### Ethics approval and consent to participate

The studies involving human participants were reviewed and approved by the Ethics Committee of the different hospitals and clinical centers, and by the University Miguel Hernández of Elche. Informed consent will be obtained from all subjects involved in the study.

##### Consent for publication

Not applicable.

##### Competing interests

The authors declare no competing interests.

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