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Digital augmentation of aftercare for patients with anorexia nervosa: the TRIANGLE RCT and economic evaluation

Janet Treasure, Katie Rowlands, Valentina Cardi, Suman Ambwani, David McDaid, Jodie Lord, Danielle Clark Bryan, Pamela Macdonald, Eva Bonin, Ulrike Schmidt, Jon Arcelus, Amy Harrison and Sabine Landau

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Extended Research Article

Digital augmentation of aftercare for patients with anorexia nervosa: the TRIANGLE RCT and economic evaluation

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This article

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Abstract

Background: High-risk patients with complex anorexia nervosa are managed in inpatient/day patient care, but re-admission rates are high, and new treatments are needed.

Objective(s): To examine the effectiveness of a digital augmentation of aftercare (ECHOMANTRA).

Design: Transition Care In Anorexia Nervosa through Guidance Online from Peer and Carer Expertise was a multicentre, parallel-group, superiority randomised controlled trial. ECHOMANTRA augmented treatment as usual was compared with treatment as usual. Patient–carer dyads were randomised using minimisation on a 1 : 1 ratio into ECHOMANTRA + treatment as usual (ECHOMANTRA) or treatment as usual alone.

Setting: Specialised United Kingdom inpatient/day patient sites (*n* = 31) participated.

Participants: Patient–carer dyads were randomised (*n* = 185 in ECHOMANTRA and *n* = 186 in treatment as usual).

Interventions: The digital ECHOMANTRA intervention included self-management tools (recovery tips videos) for patients and task-sharing materials for carers (skill-sharing video), supplemented with guided group chat sessions. All participants randomised to ECHOMANTRA + treatment as usual had access to the psychoeducational materials and joint patient/carer chat sessions were also offered.

Main outcome measures: The primary outcome was patient distress at 12 months. Other outcomes included patient distress at 18 months, and eating disorder symptoms, social and work adjustment, and carer distress and skills at 12 and 18 months.

Results: There was no evidence of an intervention effect on the Depression Anxiety Stress Scale-21 outcome for patients (*n* = 370) at 12 months, estimated effect 0.48, 95% confidence interval −0.20 to 0.23, standardised estimate (0.02, *p* = 0.87). In the economic analysis, the intervention was dominated by treatment as usual from both a health system and wider societal perspective, as ECHOMANTRA cost more and resulted in fewer quality-adjusted life-years gained. However, the uptake of the interactive component of the intervention (i.e. the facilitated and moderated online groups) was limited, with only 20% of the dyad members attending the pre-set minimal adherence level (i.e. both the patient and carer attending at least four online forum group sessions). The feedback about the intervention was predominantly positive. For example, the group facilitators were rated highly. However, some feedback was that the intervention offered too little, too late, and that a more personalised intervention would be more helpful.

Limitations: Participants were diverse (e.g. 20% were being treated under the Mental Health Act), and a large proportion had a range of comorbidities (depression, anxiety, obsessive–compulsive disorder and autistic spectrum disorders), all factors impacting prognosis. Although efforts were made to enhance inclusion, diversity in terms of gender, sexuality and race was limited, and technological barriers and/or lack of a carer may have led to exclusion. The high level of non-adherence to the group support (80% dyads) may have contributed to the non-significant findings.

Conclusions: This guided self-management and task-sharing intervention was reviewed positively by some patients and supporters; however, there was no evidence that the intervention improved outcomes over usual aftercare.

Future work: Identifying mechanisms to increase engagement such as a more personalised approach to aftercare to address the diverse needs of this patient group are needed. Greater integration between intensive and step-down services with guidance from peer workers providing support may optimise care.

Trial registration: This trial is registered as ISRCTN14644379.

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List of supplementary material

Report Supplementary Material 1 Supplementary tables and figures

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/ADLS3672).

Supplementary material has been provided by the authors to support the report, and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

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List of abbreviations

ADHD	attention deficit hyperactivity disorder
AE	adverse event
AN	anorexia nervosa
AQ-10	Autism Spectrum Quotient
ASD	autistic spectrum disorder
BCa	bias-corrected and accelerated
BMI	body mass index
CACE	complier-average causal effect
CASK	Caregiver Skills
CBT	cognitive–behavioural therapy
CBT-ED	eating-disorder-focused cognitive–behavioural therapy
CCA	complete-case analysis
CEAC	cost-effectiveness acceptability curve
CONSORT	Consolidated Standards of Reporting Trials
CSRI	Client Service Receipt Inventory
CTO	Community Treatment Order
DASS-21	Depression Anxiety Stress Scale-21
DMC	Client Service Receipt Inventory
EBCD	experience-based co-design
ECHO	Experienced Carers Helping Others
EDE-Q	Eating Disorder Examination Questionnaire
EQ-5D	European Quality of Life Scale
EQ-5D-3L	EuroQol-5 Domains, three-level version
GP	general practitioner
HEE	Health Education England
HE	Health Economics
ICER	incremental cost-effectiveness ratio
IoPPN	Institute of Psychiatry, Psychology and Neuroscience
MANTRA	Maudsley Model of Anorexia Nervosa Treatment for Adults
MAR	missing at random
MARSIPAN	multivariate imputation via chained equations
MHA	Mental Health Act
MI	multiple imputation
MICE	multivariate imputation via chained equations
NASSS	Non-Adoption, Abandonment, Scale-up, Spread, and Sustainability
NICE	National Institute for Health and Care Excellence
NIHR-HTA	National Institute for Health and Care Research, Health Technology Assessment
OCD	obsessive–compulsive disorder
OCI-R	Obsessive Compulsive Inventory – Revised
ONS	Office for National Statistics
PPI	patient and public involvement
QALY	quality-adjusted life-year
QED	Quality Network for Eating Disorders
RCT	randomised controlled trial
SAE	serious adverse event
SAP	statistical analysis plan
SDQ	Strengths and Difficulties Questionnaire
TAU	treatment as usual
TIDieR	Template for Intervention Description and Replication
TMG	Trial Management Group
TRIANGLE	Transition Care In Anorexia Nervosa through Guidance Online from Peer and Carer Expertise
TSC	Trial Steering Committee
WSAS	Work and Social Adjustment Scale

Plain language summary

Background

Transition Care In Anorexia Nervosa through Guidance Online from Peer and Carer Expertise aimed to examine whether offering a digital programme (ECHOMANTRA), containing information and online group support for patients with anorexia nervosa and their nominated supporters, could reduce patient distress and improve other outcomes in the 18-month period after leaving intensive treatment (inpatient or day care). The study also examined whether ECHOMANTRA is a good value for money to the National Health Service and the wider economy.

Method

Patients and a nominated supporter (371 pairs) were recruited and split into two groups at random: (1) usual treatment plus access to the ECHOMANTRA programme and (2) usual treatment alone.

Results

There were no differences between groups in the outcomes measured, which included patient distress, eating disorder symptoms, quality of life, social and work adjustment and carer distress and skills. ECHOMANTRA did not demonstrate good value for money. However, only 20% of participants allocated to ECHOMANTRA joined more than four online group sessions (the minimal recommended participation).

Participant feedback

Patients and their supporters reported inadequate planning and support following discharge from hospital. Patients reported low confidence in their ability to recover, and a need for more continuity in their care. Carers echoed the need for a supportive transition process. Several aspects of the ECHOMANTRA programme were welcomed, with the mixed patient/supporter online groups and online group facilitators experienced as particularly helpful. Participants were generally positive about the written and recovery tip videos. However, several suggested that more personalised content and access options were needed.

Conclusions

ECHOMANTRA failed to show a benefit overall, which may reflect the limited uptake of the online groups and the broader access to carer support outside of the study. Together with participant feedback, these findings suggest that a more personalised programme, with more integration with clinical teams, may lead to increased engagement with the virtual elements of support offered by ECHOMANTRA.

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Scientific summary

Background

Anorexia nervosa (AN) is a serious mental illness, typically developing in adolescence. It often runs a protracted course, leading to adverse outcomes, reduced quality of life and high costs. The incidence of female cases presenting to primary care in the UK pre COVID-19 was approximately 12 cases per 100,000, but a large increase followed the pandemic. Eating disorder-related disability-adjusted life-years are high both for patients and their carers. There is a large amount of uncertainty about optimal treatment for AN particularly for the subgroup with a protracted and severe form of illness admitted for inpatient/day patient care. Transitions from inpatient/day patient care can be difficult with up to 50% of patients suffering a relapse and mortality in the year following admission increased 10-fold. In two previous proof-of-concept studies conducted within National Institute for Health and Care Research-funded programmes, we found that a guided self-management approach for patients and a task-sharing approach for carers had benefits on both patient and carer outcomes. In a small feasibility study, we found that an intervention combining these interventions improved outcomes.

Objectives (list of research questions)

The aim of this study was to examine the effectiveness of a digital augmentation of transition treatment (ECHOMANTRA) offered to patients and their nominated carer/support person (participant dyads) in addition to usual care for AN. The specific aims were to assess:

- patient distress at 12 months (primary outcome)
- other patient outcomes, including patient distress at 18 months, patient motivation and ability to change, eating disorder symptoms, social and work adjustment, and days in hospital
- cost-effectiveness of ECHOMANTRA for patients at 12 months
- carer distress and skills at 12 and 18 months
- adverse events (AEs) during the study
- process aspects of the study, including adherence to treatment and patients and their carer/supporters' experiences of receiving and supporting treatment, respectively, in the trial by conducting nested qualitative studies and online surveys about both treatment as usual (TAU) alone and with ECHOMANTRA augmentation.

Methods

Design

We undertook a pragmatic, multicentre, parallel-arm, randomised trial with both clinical and health economic evaluation. We further embedded a qualitative process evaluation to understand opportunities and barriers in ECHOMANTRA and usual care. Patients were randomised to receive TAU alone, or augmented with ECHOMANTRA, a digital intervention containing guided self-management for patients and support skills for carers. The primary outcome was patient distress at 12 months post randomisation.

Settings

Thirty-one specialised inpatient or day patient eating disorder services in England and Scotland participated in the study.

Participants

The final inclusion criteria were:

a. AN patient aged 16 years or over.

b. Patients with a *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition diagnosis of AN or atypical AN, with a body mass index (BMI) of ≤ 18.5 kg/m^2 at any stage in the recruitment window (i.e. from admission until 4 weeks post discharge).
c. Patient must have a carer who is willing to participate. (Note that carer is inclusive of any family member or friend who is willing to participate and able to provide some aftercare support.)
d. Informed consent is received any time after admission until 4 weeks post discharge from inpatient/day patient care.
e. Patient–carer dyads are able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and the internet in order to use the study's website.

The final exclusion criteria were:

a. When consented into the study, the patient is not either:
    i. admitted to hospital
    ii. or attending day care for a minimum of 3 days/week

b. The patient has an insufficient knowledge of English.
c. The patient has severe mental or chronic physical illness needing treatment in its own right (e.g. psychosis, diabetes mellitus, cystic fibrosis etc.).
d. The patient is pregnant.
e. The patient–carer dyad has previously received treatments involving ECHOMANTRA materials.
f. Baseline measures have not been completed by the dyad.

Recruitment

There was a two-stage, written, informed consent process. Eligible patients who consented to participate themselves in the trial were asked to give contact details of a carer who might participate with them. After consent was obtained from both parties, baseline assessment was undertaken prior to randomisation.

Randomisation

Patient–carer dyads were randomised via an online system hosted by the King's Clinical Trials Unit as a single unit on a 1 : 1 ratio into either ECHOMANTRA + TAU [ECHOMANTRA] or TAU alone using minimisation method. Minimisation factors consisted of AN severity (binary severity: BMI ≥ 15), and study site (31 study sites). Most assessments were self-reported by patient or carer and hence not blind where assessment took place after randomisation. However, as baseline assessments were carried out before randomisation, these were blind. The statisticians remained partially blind (knowing only coded trial arm membership) until as late as possible into the primary analyses being conducted.

Intervention

The digital ECHOMANTRA intervention was accessed via the study website. Materials for patients included a toolkit (in written and video vignette form). Patients were also invited to a biweekly anonymous chat group. The groups were facilitated by early career psychologists with lived experience (direct and indirect). The groups followed a sequence of eight topics which ran consecutively throughout the study. The group format involved (1) a scene setting video introduced by the facilitator, (2) icebreaker question, (3) discussion around the topic of the video and (4) facilitator summary of implications and plans from participants. A variety of scene setting videos introduced each topic. On alternative weeks, a joint (patients and carers) chat group following the same format but with different topics was held. Carers were invited to a biweekly chat group which followed a similar format to the groups above. Transcripts from the chat group were posted on the website and used in weekly supervision meetings. Adherence to study intervention (ECHOMANTRA) was defined as both patient and carer attending at least four online forum group sessions.

Outcome measures

The effectiveness of ECHOMANTRA was evaluated at 12 and 18 months post randomisation. In addition to baseline recording, measures were collected monthly post randomisation to assist with data modelling and participant retention. Our primary outcome was patient self-reported distress using the Depression Anxiety Stress Scale-21 (DASS-21). Secondary outcomes included patient self-reported measures of BMI and eating psychopathology, visual analogue scale measuring motivation and ability to recover; psychosocial functioning (assessed using the Work and Social Adjustment

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Scale). Carer distress was measured using the DASS-21, and their understanding of helpful skills was assessed by the Caregiver Skills scale. AEs were reviewed by two independent clinicians. For the health economic analysis, health utility scores for patients only were measured using the EuroQol-5 Domains, three-level version instrument at baseline and 12 months. These were transformed into quality-adjusted life-years (QALYs) using published UK population tariffs calculated using the time trade-off method. Data on health service utilisation, productivity loss and patient out-of-pocket expenses were collected at baseline and 12 months using a modified online version of the Client Service Receipt Inventory.

Sample size

An a priori sample size calculation of n = 380 dyads was computed as being sufficient to detect a standardised effect size of Cohen's d = 0.4 for patient DASS-21 at 12 months post randomisation. The power to detect such a difference between ECHOMANTRA + TAU and TAU alone was 90% with the calculation based on a two-tailed t-test at a significance level of 5% and allowing for attrition rates observed in previous studies (30% at 12 months).

Statistical analysis

The primary outcome, patient DASS-21 at 12 months, and secondary patient and carer outcomes were formally compared between trial arms using an intention-to-treat approach. A detailed statistical analysis plan was developed and agreed with the Trial Steering Committee before database lock and analyses. As there were considerable missing values in outcome variables and non-adherence with ECHOMANTRA predicted later dropout from data collection, multiple imputation (MI) was used to adjust for missing data biases. We used the multivariate imputation via chained equations algorithm with 100 imputations.

We carried out three sensitivity analyses for the primary outcome to investigate the impact of the changes on our findings: (1) estimating causal effect of ECHOMANTRA receipt rather than of offer, (2) excluding three patients who did not meet eligibility criteria of BMI < 18.5, (3) excluding patients recruited after pandemic start (after 11 March 2020). Finally, reports of patient or carer AEs and patient concomitant medications were summarised tabulating various categories overall and by trial arm.

Economic evaluation

Economic analysis was performed from both healthcare system and broader societal perspectives, including productivity impacts on patients from lost employment/volunteering, and out-of-pocket expenses. The primary outcome in the economic analysis was incremental cost per QALY gained. The analysis was conducted on an intention-to-treat basis, with missing data imputed and costs reported in 2022 UK pounds. The time horizon was 12 months. Discounting was not applied given short duration of follow-up. Statistical uncertainty was explored through bootstrapping 1000 randomly resampled pairs of costs and outcomes with cost-effectiveness planes and cost-effectiveness acceptability curves showing the likelihood of ECHOMANTRA being cost-effective at different willingness-to-pay levels generated. As a sensitivity analysis, we conducted additional economic analyses for complete cases only, that is, trial participants with data at baseline and follow-up. Unfortunately, we were unable to extract reliable data on hospital service use from NHS Digital, NHS National Services Scotland Information Services Division and NHS Wales Informatics Service.

Results

In the screening phase, 960 patients with AN across 31 specialist day patient/inpatient services were assessed between July 2017 and July 2020. Eight hundred patients were deemed eligible, 409 patient–carer dyads consented to take part in the study and 371 dyads were randomised. Of these, 186 were allocated to TAU alone, and 185 to TAU alone plus ECHOMANTRA.

Patients were predominantly female, white, single, aged 25–26 years, with a median illness duration of 5 years and median BMI of 15.9 at baseline. The majority (76%) were recruited from inpatient care, including 19% currently admitted under the Mental Health Act (MHA) [16% had previous admissions (median 2) under the MHA]. Patient comorbidity included depression (62%), anxiety (59%), obsessive–compulsive disorder (16%), autistic spectrum disorder (5%) and attention deficit hyperactivity disorder (2%). Most carers were mothers aged 50 years, although 30% were

males and 17% were partners. Most carers were white, married, spoke English as their first language, were university educated and in paid employment. Overall, 68% of the sample provided primary outcome data with more missing values in the intervention arm [TAU, *n* = 143/186 (76%); ECHOMANTRA + TAU, *n* = 110/185 (59%)].

Our pre-specified criterion for adherence with ECHOMANTRA was not met by 80% of dyads randomised to ECHOMANTRA + TAU.

At 12 months, no differences were found between the two groups in either primary patient outcome [estimated effect 0.48, 95% confidence interval (CI) −0.20 to 0.23, standardised estimate 0.02, $p = 0.87$] or secondary patient and carer outcomes. Sensitivity analyses showed that the non-significant finding for the primary outcome was robust to changes in eligibility criteria (e.g. recruiting patients with atypical anorexia, or the onset of the pandemic).

In the economic analysis, ECHOMANTRA was dominated by TAU, as it cost more (£5948, 95% CI −£6297 to £17,786) and resulted in fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010). From the societal perspective, ECHOMANTRA was dominated by TAU with higher costs (£3351, 95% CI −£9253 to £15,371) and fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010). From the health system and societal perspectives, there is an 11.5% and 25% probability of being cost-effective at a willingness-to-pay threshold of £20,000 per QALY gained.

Over time, most outcome variables improved, although patients remained symptomatic. However, motivation for change reduced, and self-rated ability to change remained low. No differences in AEs were found between groups. Most of the adverse effects recorded were related to signs of relapse of the eating disorder, that is, weight loss. Five patients died during the study (three in TAU and two in ECHOMANTRA arms). Most patients were no longer in hospital in the period from 9 to 12 months.

Feedback from patients and carers

The process evaluation used a mixed-methods approach to obtain participant feedback about optimising transition support and to understand factors influencing engagement with ECHOMANTRA intervention. A major theme from both patients and carers was ambivalence about the wish for treatment and recovery. This was reflected by poor engagement with aspects of the study and reduced self-rating of motivation at the end of trial. Both patients and carers emphasised the need to tailor transition support to the stage of illness (ambivalence) and the diverse forms of illness with signposting to aid navigation to the appropriate tools. Many noted that the remote, anonymous design with a lack of individualisation was unappealing. Patients and carers recommended more integrated planning and liaison between inpatient and outpatient services. Carers particularly valued connection and support from others. Indeed, many carers in the TAU study arm spoke about accessing carer support groups outside of the trial (a factor that may have minimised the difference between groups). The burden of care and sense of hopelessness in the face of ambivalence or previous failed treatments contributed to lack of engagement.

Conclusions

Implications for health care

Engagement with ECHOMANTRA was poor and not associated with an improved transition outcome.

The feedback from participants suggested that a more personalised and tailored form of intervention, with adjustments to adapt to the range of diversity in terms of social demographic factors, comorbidity and/or stage of illness, is needed. For example, a transition service adapted to the stage of illness (like the First episode and Rapid Early intervention for Eating Disorders (FREED) model of outpatient care) may be of value. Furthermore, flexible integration between the range of services and community support is essential to cover and respond to the variable range of needs in this patient group. Hopefully, the initiative to have joint commissioning of inpatient and outpatient services will facilitate this. For example, the Healthy Outcomes for People with Eating disorders (HOPE) model in Oxford (an early adopter of local-based commissioning) developed a care pathway with a thread of continuity across all services.

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Recommendations for research

Following the Medical Research Council process of developing complex interventions, the next steps for adult patients with AN would involve building upon trials using the Experienced Carers Helping Others (ECHO) and Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA) approaches across Europe.

Building on MANTRA for aftercare

One example of aftercare is the specialized post-inpatient psychotherapy for sustained recovery in anorexia nervosa via videoconference (SUSTAIN) trial for adult aftercare is in progress in Germany. This aligns with Transition Care In Anorexia Nervosa through Guidance Online from Peer and Carer Expertise (TRIANGLE), and the protocol is published (Giel KE, Martus P, Schag K, Herpertz S, Hofmann T, Schneider A, et al. Specialized post-inpatient psychotherapy for sustained recovery in anorexia nervosa via videoconference–study protocol of the randomized controlled SUSTAIN trial. *J Eat Disord* 2021;**9**:61). The SUSTAIN design involves video psychotherapy support for adult patients transitioning from inpatient care. Following COVID, this is widely accepted and used in eating disorder treatment in the UK. Therefore, this intervention would facilitate a personalised and integrated approach and address the feedback on this issue in TRIANGLE. We would plan to use similar measures to describe the clinical features and outcomes. This would allow for a meta-synthesis of the results across trials. SUSTAIN does not include testing an intervention for carers. Given that the broad impact of improved psychoeducation for carers of adults with eating disorders has been widespread, and many of the materials are disseminated, we suggest that signposting the existing resources for carers could be part of the standard package.

Building on ECHO for aftercare

The results of MANTRA-based [Wittek T, Truttmann S, Zeiler M, Philipp J, Auer-Welsbach E, Koubek D, *et al.* The Maudsley model of anorexia nervosa treatment for adolescents and young adults (MANTRa): a study protocol for a multi-center cohort study. *J Eat Disord* 2021;**9**:1–12; Wittek T, Zeiler M, Truttmann S, Philipp J, Kahlenberg L, Schneider A, *et al.* The Maudsley model of anorexia nervosa treatment for adolescents and emerging adults: a multi-centre cohort study. *Eur Eat Disord Rev* 2023) and ECHO-based (Philipp J, Truttmann S, Zeiler M, Franta C, Wittek T, Schöfbeck G, *et al.* Reduction of high expressed emotion and treatment outcomes in anorexia nervosa – caregivers' and adolescents' perspective. *J Clin Med* 2020;**9**:2021; Philipp J, Franta C, Zeiler M, Truttmann S, Wittek T, Imgart H, *et al.* Does a skills intervention for parents have a positive impact on adolescents' anorexia nervosa outcome? Answers from a quasi-randomised feasibility trial of SUCCEAT. *Int J Environ Res Public Health* 2021;**18**:4656; Zeiler M, Philipp J, Truttmann S, Wittek T, Kopp K, Schöfbeck G, *et al.* Fathers in the spotlight: parental burden and the effectiveness of a parental skills training for anorexia nervosa in mother–father dyads. *Eat Weight Disord* 2023;**28**:65) trials for adolescent patients in Austria have been published. It would be of interest to examine an aftercare or transition care MANTRA intervention in adolescents which could be informed by these studies.

Learning from TRIANGLE

We have written a further report detailing the lessons learned from the TRIANGLE study (Ambwani S, Coull E, Cardi V, Rowlands K, Treasure J. Every mistake is a treasure: lessons learned from the TRIANGLE trial for anorexia nervosa. *Int J Eat Disord* 2024;**57**:1330–6). In this report, we highlight strategies deployed to address trial logistics (e.g. enrolment, retention), challenges (e.g. modest uptake) and the vital role of people with lived experience at every stage of the research process. We hope that these lessons learned will be beneficial to future treatment researchers.

What impacts on the prognosis of anorexia nervosa: the implication for staging anorexia nervosa

The project would combine existing databases from trials and clinical electronic records to determine prognostic features and possible staging models for AN.

Support for the diversity of carers of eating disorders (fathers, partners, siblings) in different cultural contexts across the spectrum of eating disorders

The current model of carers support is designed for parents (particularly mothers) of white, highly educated patients with AN. There is a need to develop materials for a wider spectrum of cases and consider involvement of other carers.

Trial registration

This trial is registered as ISRCTN14644379.

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Chapter 1 Introduction

Anorexia nervosa (AN) develops in early adolescence[1] and runs a protracted course with two-thirds of cases persisting for 9 years and a third for over 20 years.[2] In general, earlier intervention is linked with a better prognosis.[3] However, it is a dangerous illness with one of the highest mortality rates of all psychiatric disorders.[4] Those with high medical risk are managed in hospital and remain dependent on their wider support systems.[5] It is this subgroup of patients that are the focus of the transition care in anorexia nervosa through guidance online from peer and carer expertise (TRIANGLE) study.

Inpatient/day patient treatment for severe anorexia nervosa

Approximately 50% of adults admitted for specialist inpatient treatment in the UK have been ill for over 5 years, often with several previous hospitalisations.[19] The length of hospital stays for AN are greater than that for other psychiatric disorders,[20] and the parameters of risk and length of stay vary across and within different health systems.[5,8]

Transitions from inpatient treatment

Unfortunately, the gains made in hospital are often not sustained. A systematic review reported a rate of relapse between 20% and 50%.[9] Failed discharges, with most relapses occurring within 60 days after discharge, are common.[10] The high human cost for this group of patients is illustrated by the standardised mortality ratio in the year following admission in the UK, which was 11.5 [95% confidence interval (CI) 6.0 to 17.0], in people aged 15–24 years and 14.0 (95% CI 9.2 to 18.8) for adults aged 25–44 years.[11] A data linkage study in the UK found that the rates of re-admissions for AN were increasing at a faster rate than the increase in first recorded episodes.[12] Feedback from patients and carers has described the many ways the transition from intensive care (inpatient or full-time day patient) back to home is poorly managed.[13] Aftercare needs careful, integrated planning.[14]

Examples of aftercare

Various models of care have been used to support the transition from hospital to home. Two systematic reviews were published in 2021.[15,16] Clark Bryan *et al.* described the forms of the various interventions using the Template for Intervention Description and Replication (TIDieR) framework.[15] A total of 14 interventions were included in the review, 9 of which were interventions for the individual delivered through face-to-face or digital formats , such as videoconferencing,[17] with/without guidance, 3 of which examined the impact of fluoxetine, and 2 of which used stepped-care bridging approaches. Three of these studies aimed to optimise the support provided by carers/family members (either alone n = 1; or joint carer/patient n = 2). The review by Giel *et al.*[17] included seven randomised controlled trials (RCTs) (with three others registered). All of those trials had high levels of dropout, particularly those that used pharmacological treatment. Guided self-help interventions also had limited uptake and high dropout, whereas more intensive interventions such as cognitive–behavioural psychotherapy reduced the rate of relapse.[16] A recent small audit project described an integrated, stepped, enhanced cognitive–behavioural therapy service model, starting with inpatient care with a target body mass index (BMI) of 19 (n = 13 weeks), followed by day care (n = 7 weeks) and then 40 sessions in outpatient care, and they reported reduced relapse rates compared with treatments with a less cohesive model of care.[18,19] However, it was not possible to continue to deliver this model of care when COVID-19 restrictions disrupted day patient care. The paucity of research in this area means that the evidence base for this costly and disruptive form of treatment is insufficient to reliably inform practice.[20–24]

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Commissioning services for severe anorexia nervosa (inpatient care)

In the UK, before 2020, inpatient services for eating disorders were nationally commissioned with approximately 50% of inpatient care devolved to the independent sector. In contrast, for the most part, community services for eating disorders were locally commissioned. There were approximately 450 commissioned beds which were insufficient to match the need, leading to waiting lists with prioritisation for those who are gravely ill. To free beds to admit high-risk patients, many patients are discharged at a suboptimal weight with continuing symptoms.

There has been a recent change in the commissioning context of inpatient care in England with a move from national to regional commissioning of specialist eating disorder services. A few services were chosen to be early adopters of this form of commissioning and have written about their experience.[25] The National Institute for Health and Care Excellence (NICE) guidelines recommend that a year of psychotherapy is offered to people post discharge.[22] However, community resources for adults with eating disorders have not kept pace with the increasing prevalence and severity of eating disorders, and consequently there are long waiting times[19] for outpatient and day patient services, with many patients having support given too late, or not at all, post discharge. Another barrier to a smooth transition is that specialised hospitals may be some distance from the patient's home and community services, which may obstruct the planning and development of an integrated transition pathway.

The impact of COVID-19

The COVID-19 pandemic, with lockdown in the UK starting in March 2020, was associated with a worldwide increase in the prevalence of AN,[25,26] and the demand for eating disorder beds markedly increased. At the same time, intensive services had reduced capacity. This led to long waiting lists and a distressed workforce. A longitudinal, cohort study (between July 2018 and March 2021) of adult specialist eating disorder inpatient services, covering a population of 3.5 million in South East England within the new provider collaborative commissioning framework, reported 351 referrals, an increase by 21% during the pandemic.[18] Waiting times increased from 33 to 46 days, which led to a disruption in the newly developed integrated transition pathway, and poorer outcomes ensued. Thus, the pandemic amplified an already existing need for improvements to care pathways for patients with severe AN in the UK.

Predictors of outcome following inpatient care

A recent meta-analysis (using data from 35 studies) to determine the predictors of the outcome of eating disorders from various treatments has been produced.[27] The predictors of relapse included a higher level of care, general psychiatric comorbidity and higher eating disorder psychopathology. A better outcome was associated with higher motivation for change, and nutritional markers (higher leptin, higher meal energy density/variety, higher BMI/weight/body fat), AN-restricting (vs. AN-binge purge) subtype diagnosis and an older age of eating disorder onset.

Given the increased attention given to early intervention, there has been a focus on the duration of illness and whether this predicts a poor outcome and is of relevance in terms of staging the illness. One review found that a long duration of illness predicted a poor outcome[28]; however, another mixed-diagnosis, systematic review did not.[29] One possibility is that protracted starvation, with its impact on the structure and function of the brain,[30] has a larger influence on the course of the illness than other eating behaviours. Several studies report that weight gain attained during inpatient care predicts the outcome.[10,31–34] However, this variable is influenced by patient motivation, which also impacts on the outcome.[32]

Comorbidity as a prognostic factor

Comorbidity is a factor that also impacts on eating disorder outcome. For example, anxiety and depression are associated with a poorer outcome.[27,28,35,36] Comorbid autism spectrum traits were associated with a poorer general outcome in a Swedish study of a cohort of patients with AN recruited in mid-adolescence and followed for 30 years.[37]

Another cohort of Swedish patients with an eating disorder and a registered ASD diagnosis [134 (4.2%) individuals] had many features characteristic of a more severe illness, such as the use of tube feeding, longer periods of inpatient care and increased levels of suicidal behaviour.[38] Also, adolescents with AN from the UK with autistic spectrum disorder (ASD) traits [*n* = 23/150 (23%)] had significantly more inpatient/day patient service use and medication at baseline.[39] Obsessive–compulsive disorder (OCD), obsessiveness and depression have also been found to be negative predictors of outcome.[31,40,41]

Interpersonal factors and relationships as prognostic factors

Several studies and systematic reviews have examined how interpersonal relationships within the family might impact on the outcome of AN (*Figure 1*). For example, high expressed emotion (particularly, parental criticism) was associated with a poor outcome,[42,43] as was parental accommodating behaviour.[44] However, skills-based treatment mitigated the relationship between patient and carer distress.[44,45,46,47]

Theoretical framework: the cognitive interpersonal model

The intervention used in TRIANGLE was based on the cognitive interpersonal model[48] (see *Figure 1*). This model includes the factors (genetic, developmental and environmental) that predispose to the development and maintenance of AN. The elements within the model have been elaborated over time[49,50] as more details about the aetiology of AN have been discovered.[51,52] For example, large studies have revealed that the genetic risk factors associated with AN include a similar profile to a range of psychiatric disorders, including OCD and anxiety,[53,54] and to a metabolic profile that includes insulin sensitivity and low BMI.[52]

The predisposing psychological traits include perfectionism,[55] anxiety[56] and difficulties tolerating uncertainty.[57] Sustained poor nutrition contributes to the perpetuation of the problem through a detrimental impact on both brain and body. For example, brain cortical thickness is reduced by 6% early in the illness.[30,58] Anomalies in social cognition, memory and aspects of cognitive and emotional processing are found.[59,60] Some secondary effects of the eating disorder become valued in the context of the eating disorder. For example, emotions are suppressed, which is valued for those with difficulties regulating emotions, and rule-driven behaviour is a comfort to those who value certainty.[61] The development of a mature, healthy identity is compromised, and an anorexic identity becomes dominant. The targets of

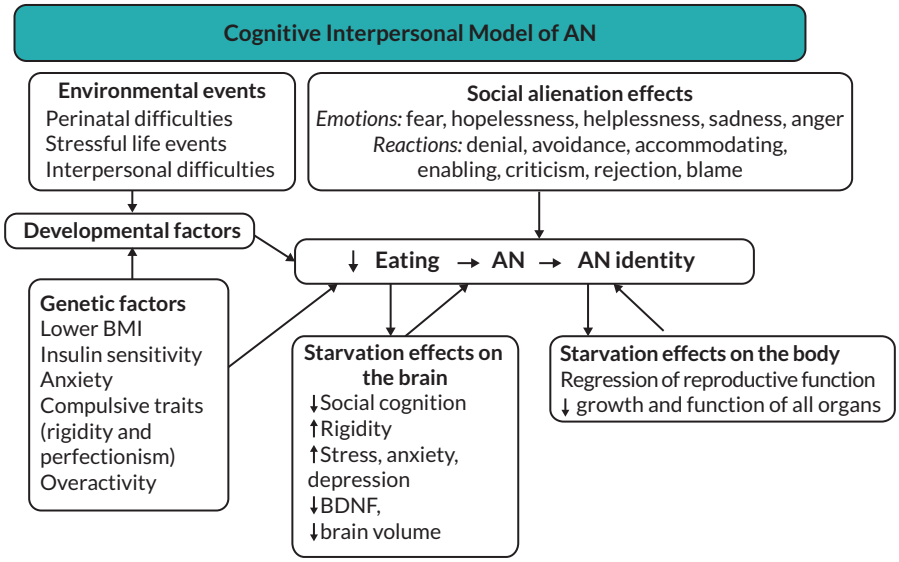

FIGURE 1 The cognitive interpersonal maintenance model depicting how genetic, developmental and environmental factors can predispose to the development of AN and how secondary starvation effects on the brain, body and social interactions can serve to maintain the problem. BDNF, Brain-derived neurotrophic factor.

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treatment are to uncouple the eating disorder from these underlying traits which can be used productively towards the goals and values of a recovered identity.

In addition, the illness has a profound effect on close others who often provide a great deal of support but who can become anxious, depressed and frustrated. This understandable emotional response leads to high expressed emotion (such as overprotection and criticism) associated with an adverse outcome.[62] In a network analysis examining associations between carer and patient functioning, we found that carer depression/stress and emotional overinvolvement and patients' depression were linked, as were patients' depression and carers' accommodation.[63] Accommodating behaviour has also been found to impair the outcome of treatment for OCD symptoms[64] and it is possibly the mechanism which mediates between obsessive–compulsive traits and a poor outcome in AN.[44] The targets of treatment towards the interpersonal aspects of the model are to reduce accommodating/overprotective and critical behaviours and to alleviate depression in both the patient and their support network.

The development of the ECHOMANTRA intervention

The TRIANGLE project developed from a programme of work developing new interventions for patients with severe AN set within the ARIADNE programme grant. Two studies (one for individuals themselves and one for close others) were developed and tested in pilot studies within that project. In the TRIANGLE study, these two forms of treatment were combined to form a hybrid intervention.

The development of the intervention for patients

A feasibility study of a guided self-management intervention Maudsley Model of Anorexia Nervosa Treatment for Adults (iMANTRA; *n* = 41 participants based on the MANTRA[65] to support transition) was undertaken. This showed potential, although the adherence to the intervention was limited. Further, feedback from people with lived experience and pilot studies, which provided educational material through podcasts and vodcasts to support eating and/or improve mood, showed promise[66,67] and led to the codevelopment of a podcast library of recovery tips and a self-care toolkit, RecoveryMANTRA. This was used as a guided self-management intervention to augment the transition into outpatient treatment in the SHARED trial.[68] People in the RecoveryMANTRA arm of the study experienced a greater reduction of anxiety and a better working alliance with their clinic therapist at the end of the intervention.[69] MANTRA has been further adapted for a group context70 and for adolescents and young adults.[71,72]

The development of the intervention for carers

The Carers' assessment, skills and information sharing (CASIS) feasibility study (*n* = 178 participants), developed in conjunction with people with lived experience, demonstrated that a guided skill-sharing and educational intervention experienced carers helping others (ECHO), led to small but sustained improvements in patient symptoms as well asreduced relapse rate and caregiver burden.[6,73] The intervention for carers in TRIANGLE used an adaptation of ECHO.[74] Supplementary digital materials for carers were coproduced with people with lived experience and adapted from the materials disseminated in books, videos, podcasts and workshops.[75,76]

The development of the hybrid ECHOMANTRA intervention

For the TRIANGLE study, it was decided to combine the two (carer and patient) aftercare approaches using the upgraded ECHO intervention for carers and RecoveryMANTRA for patients. A pilot study, in which the two interventions ECHO and RecoveryMANTRA were given simultaneously to patients and carers transitioning from inpatient care, led to a decrease in the relapse rate and an improvement in both patient and carer well-being.[77] The aim of this two-part, complex intervention, ECHOMANTRA, was to provide a digital bridge to support both patients and their carers, with the potential to offer the reach and scale to augment the current fragmented, under-resourced, aftercare (for further details about the ECHOMANTRA intervention using the TIDieR framework, see *Chapter 2*).

Summary and methodological rationale

The TRIANGLE trial was designed to evaluate the clinical effectiveness and cost-effectiveness of the hybrid ECHOMANTRA intervention which offered information and support to both patients and their community support (carers) to manage the transition from hospital to home in an entirely digital format. Preliminary evidence for the efficacy of each of these components had been obtained through a proof-of-principle trial.[77] This study was the next step to examine the clinical effectiveness and cost-effectiveness through a pragmatic, adequately powered, multicentre RCT.

Research objective

The primary objective was to assess the effectiveness of ECHOMANTRA with treatment as usual (TAU) compared to TAU alone in reducing patient depression, anxiety and stress symptoms at 12 months post randomisation. Secondary objectives were to assess the effectiveness of ECHOMANTRA with TAU compared to TAU alone in relation to all other outcomes for both patients and carers at 12 and/or 18 months such as patient eating disorder psychopathology, and carer depression, anxiety and stress symptoms and skills to manage the illness (for a list of these outcomes, see *Chapter 2*). The protocol was published at an early stage in the study,[74] and the statistical analysis plan (SAP) was developed prior to undertaking any data analysis. Cost-effectiveness of ECHOMANTRA with TAU compared to TAU alone was also assessed (see *Chapter 4*). In addition, patients' and carers' subjective experiences of ECHOMANTRA compared with TAU, treatment fidelity of the ECHOMANTRA intervention, and the implications for roll-out in the NHS were assessed using a mixture of quantitative and qualitative methods (see *Chapter 5*).

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Chapter 2 Trial design and methods

Introduction

This chapter provides details related to the trial design and methods used in the TRIANGLE trial pertaining to the data analysis documented in the SAP (internal document), including updates from the protocol which was published during the early stages of the study.[74] For details of the design and methods used in the process evaluation, see *Chapter 5*.

Patient and public involvement

We incorporated patient and public involvement (PPI) throughout the course of the study, at various stages of the study, including study objectives, design, intervention development, management and dissemination. PPI activities within each of these areas are described in detail in *Chapter 6*. The Trial Steering Committee (TSC) PPI members received remuneration for their extensive contributions to the trial management, following the NIHR guidance on PPI recognition.[78]

Study objectives

The overall aim of the TRIANGLE trial was to examine the clinical and cost-effectiveness of adding a novel skill-sharing intervention (ECHOMANTRA) to TAU (TAU; aftercare post inpatient or intensive day care treatment) for patients with AN and their carers.

The primary objective was to examine whether adding the ECHOMANTRA intervention to TAU improves patient distress (depression, anxiety and stress symptoms) at 12 months post randomisation.

The secondary objectives were to:

1. examine whether adding ECHOMANTRA to TAU improves other aspects of patient distress (e.g. eating disorder symptoms, social functioning), cost-effectiveness and service use
2. examine whether adding ECHOMANTRA to TAU improves carer distress (i.e. depression, anxiety and stress symptoms, carer skills), at 12 and/or 18 months post randomisation
3. assess patients' and carers' feedback on the study protocol and intervention (e.g. via feedback forms and interviews with subgroups of participants).

As outlined above, the methods for the statistical analysis included in this chapter reflect the analysis of the primary objective and first secondary objective only, as per the SAP (internal document). The design and methods related to secondary objective 3 can be found in *Chapter 5*.

Study approval and monitoring

The trial was approved by London – Camberwell St Giles Research Ethics Committee (REC), (REC Reference: 16/LO/1377). It was also approved by local research and development departments at each NHS participating trust. The trial was monitored by the TSC and the Data Monitoring Committee (DMC). Both committees met at least once per year and at most twice per year during trial set-up, recruitment and follow-up. In total, there were 7 TSC and 7 DMC meetings during the trial and 40 Trial Management Group (TMG) meetings. The DMC monitored the trial database reports, including all serious adverse events (SAEs) within the RCT at each committee meeting. The TSC were updated on the trial progress at each meeting and invited to share comments or suggestions on areas for improvement, for example, strategies on improving recruitment. The TMG [comprising the chief investigator, coinvestigators (including

trial manager), PPI representatives, senior and junior statisticians, and junior health economist and research assistants] met at regular intervals during the study (typically monthly) to review ongoing progress and other relevant issues such as dissemination.

Ethics statement

This research formed part of the process evaluation of the TRIANGLE intervention registered with ISRCTN: 14644379, on 8 December 2016. The qualitative components are reported in line with the Standards for Reporting Qualitative Research guidance.[79]

Study design

Study settings

The trial was co-ordinated by the Institute of Psychiatry, Psychology and Neuroscience (IoPPN), King's College London, with the chief investigator, trial manager and research assistants all based at this location. Both independent and NHS specialised inpatient and day-care treatment settings across the UK were invited to join the study (see *Figure 2* for participating sites and their geographical regions). Recruitment took place between July 2017 and July 2020, and

FIGURE 2 Participating recruitment sites by geographical region in the UK.

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follow-up was completed by July 2021. For three sites, it was necessary to provide Wi-Fi routers to allow participants to access the study website. The liaison with each site was through study champions at each site (these included local principal investigators, research nurses/assistants, clinical studies officers provided by the Clinical Research Network, or other key clinical staff from each trust, including clinicians, assistant psychologists, research assistants, occupational therapists) who informed potential participants about the study. The research assistants from the IoPPN actively assisted most sites with the recruitment process, through face-to-face recruitment visits to the units, and virtual meetings/telephone calls with clinical teams, patients and carers.

Recruitment

Screening phase

First, patients with AN were screened against several eligibility criteria by the local staff involved in the study, or by the core study research assistants, at participating inpatient/day-care units where they were receiving treatment (for full eligibility criteria, see *Table 1*). Potential participants were given a flyer and an information sheet about the study, as well as a verbal explanation of what the study would entail for them. Eligible participants who agreed to participate were consented on the basis that they would need a supporter willing to participate to be fully enrolled into the trial. The 'carer' was defined as a non-professional carer such as a family member, partner or friend. Participants were asked to provide their clinical team, or the central study team, with contact details of their carer, who then contacted them to invite them to participate. Written informed consent was thus obtained from both the patient and their carer. Once both participants in the dyad (patient and carer) had provided consent, the study team sent separate e-mails to the patient and carer with individual login details to the study website (created by Mindwave; http://mindwaveventures.com), where they could complete the baseline questionnaires. The local staff involved in the study and/or core research assistants provided guidance to complete these questionnaires via e-mail/telephone or in person. Once baseline measures were received from both the patient and carer, the dyad were randomised to either (i) ECHOMANTRA in addition to TAU or (ii) TAU only.

Randomisation

Following the completion of the baseline assessments, participants (the patient–carer dyad) were randomised (with a ratio of 1 : 1) and stratified by site and illness severity (defined by BMI < 15 and > 15 at baseline) using minimisation algorithm to receive either (1) access to the ECHOMANTRA intervention materials and TAU or (2) TAU only (control condition). This was performed with 80% probability of allocating participants to the arm that reduces the imbalance.

TABLE 1 Eligibility criteria for patient participants

Inclusion criteria

a. Aged 16 or over.
b. DSM-V diagnosis of AN or subclinical/atypical AN, with a BMI of ≤ 18.5 kableg/m^2.

N.B. Patients can be consented at a BMI of over 18.5 kg/m^2 if they were ≤ 18.5 kg/m^2 when first admitted into hospital or when first attending day care 3 days/week or at any time within 4 weeks after discharge from hospital.

c. With a carer willing to participate. We will use a broad definition of 'carer' to include family and/or friends willing and able to provide some aftercare support.
d. Informed consent signed while patient is admitted into hospital up to 4 weeks after discharge.
e. Participants able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and the internet in order to use the study's website.

Exclusion criteria

a. The patient is not admitted to hospital or attending day care for a minimum of 3 days/week when they are consented in the study.
b. The patient has an insufficient knowledge of English.
c. The patient has severe mental or chronic physical illness needing treatment in its own right (e.g. psychosis, diabetes mellitus, cystic fibrosis etc.).
d. The patient is pregnant.
e. The patient–carer dyad has previously received treatments involving the ECHOMANTRA materials (e.g. as part of iMANTRA trial or CA-SIS study).
f. Baseline measures have not been completed by the dyad.[a]

DSM-V, *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition.
a Completion of baseline measures were not listed as official exclusion criteria in the study protocol;[74] however, this was effectively an additional exclusion criteria, given the explanation in the protocol that randomisation could only commence following completion of the baseline measures.

The allocation sequence was generated dynamically, so the next allocation was only known once a request form was triggered by the study team. A maximum of four research staff were authorised and given passwords to request randomisation (i.e. only the core research assistants and trial manager were granted these permissions). Randomisation was delivered by the King's Clinical Trials Unit online randomisation system at the IoPPN (accessible at www.ctu.co.uk). The randomisation system was available 7 days/week, and the outcome (i.e. the dyads' condition allocation) was communicated to the research team via e-mail instantly (i.e. within < 5 minutes of requesting randomisation). Once the database returned a dyad's allocation, no changes could be made.

Intervention phase

Following randomisation, all participants (patients and carers) received an electronic version of the website guide, which included instructions for logging into their account, completing questionnaires, and how to submit these to the study team. All participants (in the active or control arms) were automatically prompted (via e-mail) to complete monthly monitoring assessments and could access visual feedback charts illustrating their scores on these monitoring questionnaires for depression, anxiety, stress, social connection and weight, which they could use to track their progress in these areas over the course of the trial. In addition, participants were prompted by the research assistants by e-mail/text/telephone/post to complete five key follow-up assessments which were administered at 3, 6, 9, 12 and 18 months post randomisation. The two main follow-up assessments were administered at 12 and 18 months post randomisation.

The intervention group received additional guidance on how to access the online workbook, video library, and to reserve a place for upcoming online facilitated and moderated groups. The research assistants also offered a telephone induction to participants on how to use the website and access the materials. Participants in the intervention group who had shown signs of non-engagement during the first approximately 6 months of their participation (i.e. had not joined any online groups) were contacted by e-mail to offer further information about the study and how to engage with the intervention. All participants were given the e-mail addresses of the research assistants, whom they could contact at any time during the study for a reminder of their login details or for further support with any of the study tasks.

Blinding and protection from bias

To protect from bias, the trial statisticians were kept partially blind (only knowing trial arm codes) to participant condition allocation throughout the trial. The trial statistician (JL) became accidentally unblinded after database lock, while partial blinding (only seeing data by coded trial arm categories) was maintained for the senior statistician (SL) until the very final stages of the analyses which required unblinding. The study team requested that clinicians treating patients at participating centres were also blinded to the dyads' condition allocation. Although it was possible that clinicians at participating centres could elicit (by questioning the patient) details of the patient's condition allocation, no cases of unblinding were reported to the study team. Where a clinician was involved in the patient assessments (i.e. BMI, clinical survey, patient discharge, family therapy, SAEs, psychological concomitant mediations), the clinician was kept blind to the patient's condition allocation. As the patient and carer baseline assessments were carried out before randomisation, these were completed while blind. After randomisation, participants were unblind to their condition allocation. Most assessment were self-reported by the patient or the carer and hence not blind when the assessment took place after randomisation. The research assistants were also unblind throughout the trial. If participants had an intervention-related question, they were instructed to contact the research assistants. The trial manager and the chief investigator were kept fully blind throughout the trial. However, participants were provided with contact details for the trial manager and the chief investigator, whom they could also contact to ask questions or to seek support during the study. Participant use of the facilitated and moderated online groups in the ECHOMANTRA arm was assessed by a single research assistant who was unblind.

Interventions

Control intervention: treatment as usual

Treatment as usual was non-standardised during the trial; therefore, all participants received the care that would normally be delivered at each participating centre. In the UK, it is recommended that all eating disorder services follow

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evidence-based guidelines, such as those within the NICE guidelines.[22] For adults (aged 18 +, who make up most of our sample), the NICE (2017) guidelines recommend one of the following evidence-based psychological interventions as first-line treatment for AN: individual eating-disorder-focused cognitive–behavioural therapy (CBT-ED), MANTRA, or Specialist Supportive Clinical Management. If any of these three options are unacceptable, contraindicated or ineffective for adults with AN, the recommendation is to consider another one of these three treatments that the person has not had before, or to consider eating-disorder-focused focal psychodynamic therapy. For young people with AN (aged 16–17) of whom make up the minority of our sample, the recommendation in the NICE guidelines is to consider anorexia-nervosa-focused family therapy for children and young people (FT-AN), delivered as single-family therapy or a combination of single- and multi-family therapy. If FT-AN is found to be unacceptable, contraindicated or ineffective for children or young people with AN, the recommendation is to consider individual CBT-ED or adolescent-focused psychotherapy for anorexia nervosa.

To supplement the NICE guidelines, the Royal College of Psychiatrists have published guidance on the medical management of emergencies in eating disorders. The guidance covers the management of both physical and psychiatric aspects of the illness. The latest version of this guidance, 'Medical emergencies in eating disorders',[80] replaces the previously published guidance, 'Management of Really Sick Patients with Anorexia Nervosa' (MARSIPAN) and Junior MARSIPAN.

In addition, the Quality Network for Eating Disorders (QED) includes a set of standards for inpatient services, drawn from a range of authoritative sources, with feedback from patient, carer and expert representatives.[81] To attain accreditation, the sites undergo regular site visits, during which they must demonstrate compliance to these standards. The standards and criteria for compliance are classified in the order of priority (i.e. services must meet 100% of Type 1 standards relating to patient safety, rights or dignity; 80% of Type 2 standards; and 60% of Type 3 standards to receive the accreditation). A report is published annually providing an overview of adherence to the QED standards across the services involved (the standards and annual reports are available here: www.rcpsych.ac.uk/improving-care/ccqi/quality-networks-accreditation/eating-disorders-qed/resources). The data presented in the last report published in 2021 cover 31 inpatient eating disorder service reviews that took place between January 2019 and July 2021 (30 of which were finalised reports, and 18 of which were sites involved in the TRIANGLE trial). Ninety per cent of the services evaluated met the essential quality criteria.[82]

Furthermore, Beat (the leading eating disorders charity in the UK), the Royal College of Psychiatrists and the Academy for Eating Disorders have published guidelines relating to carer involvement, and these have been introduced into quality standards for inpatient care.[81,83] At least 70% of sites assessed met most standards under the theme 'Caring for Carers', which includes standards that relate to how services support the families and partners of patients. These include the provision of information packs to carers and making contact with carers within 48 hours of patients' admission to the inpatient ward. The adherence was lower (55% sites) for one standard related to the provision of advice to carers on accessing a statutory carers' assessment.[82]

Despite the guidelines available, there is inevitably some variation between treatment settings and in the treatment delivered at inpatient units across the UK. For example, the QED reports that the average number of beds is 13 (range 5–27) and length of stay is 107 (42–208).[82] Thus, due to local service procedures and clinical need, we were not able to be prescriptive about TAU.

ECHOMANTRA intervention

The key elements of the conceptualisation of the disorder and the treatment elements incorporated in the approach used are illustrated in *Figure 3*, which shows an outline of the features of the MANTRA cognitive interpersonal model[4] detailing how AN develops, as well as what is targeted in therapy. In addition to the standard features of cognitive–behavioural therapy (CBT), there is an increased emphasis given the social context of eating and the social reaction to the consequences of not eating, hence the hybrid nature of the intervention. Participants who received the ECHOMANTRA intervention had access to the patient and carer ECHOMANTRA materials. Patients could access an online workbook, a library of video clips, and online facilitated and moderated groups for patients and joint groups for patients and carers. Similarly, carers could access a carer workbook and a detailed carer guide, 'Skills-based caring for

a loved one with an eating disorder', as well as a library of video clips and online facilitated and moderated groups with carers, and joint groups for patients and carers. We have used the TIDieR checklist[84] to generate a detailed description of the intervention (see *Table 2*).

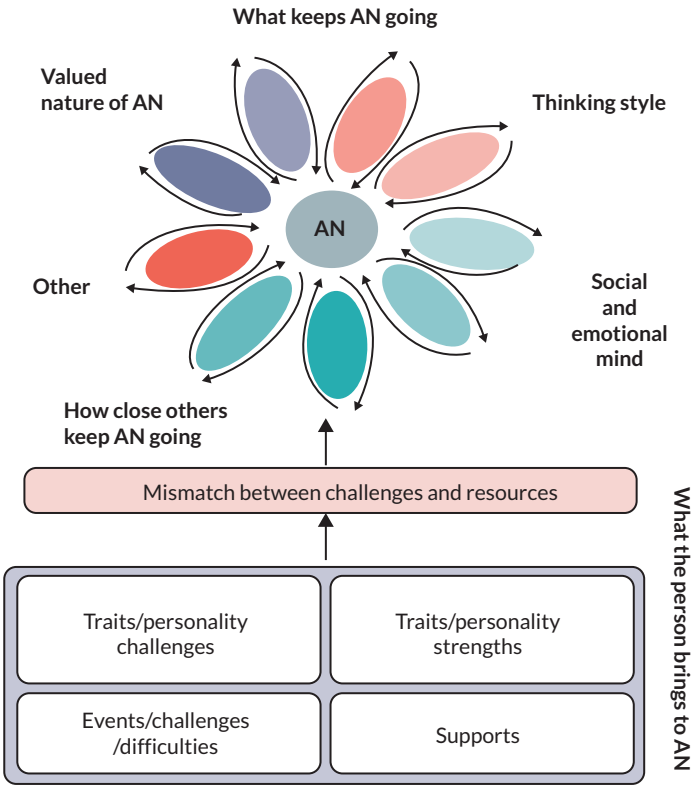

FIGURE 3 Vicious flower of AN depicting factors that contribute to the development and maintenance of AN according to the cognitive interpersonal model. Reproduced with permission from Schmidt *et al.*[85] © Taylor & Francis 2018.

TABLE 2 Template for Intervention Description and Replication Description and content of ECHO and RecoveryMANTRA intervention (i.e. ECHOMANTRA) for adults with AN and their carers

Study protocol	Cardi *et al.* 2017[74]
Item 1: Brief name of the intervention	ECHOMANTRA: hybrid carer (ECHO) and patient (RecoveryMANTRA) Maudsley Model of Anorexia Treatment for Adults (MANTRA).
Item 2: Rationale or goals	ECHOMANTRA is underpinned by the cognitive interpersonal maintenance model for AN[48–50] which details intra- and interpersonal mechanisms that maintain AN. The overall aim is to improve interpersonal relationships by focusing on building collaboration between both patient and carer and to bridge the gap between hospital and home and produce better traction for change. Carers are taught how to build communication skills that foster understanding and compassion about the illness and strategies for behaviour change that can be helpful to use in the face of ambivalence and resistance (e.g. motivational interviewing, emotion-focused therapy). The aim is to share skills with carers that can interrupt patterns of behaviour that can perpetuate the illness such as reacting with unhelpful emotional responses such as overprotection and/or criticism and using avoidance strategies such as accommodating to the illness. The intervention for patients also focuses on the cognitive interpersonal model and the processes that maintain the disorder such as the cognitive, emotional and biological factors that can allow the eating disorders to take a hold. It also includes recovery tips from people with lived experience to help develop self-compassion and strategies that can be used in the reconstruction of an identity independent of the eating disorder.
Item 3: What materials were used	Patients and carers randomised to receive ECHOMANTRA receive access to a multimodal online toolkit with separate patient and carer workbooks; a video library compiled of short, relevant video clips (n = 134); and access to secure guided online chat groups (patient-only, carer-only and joint patient–carer groups) aimed to promote skill development, emotion regulation, social connections and development of a recovery identity.

continued

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TABLE 2 Template for Intervention Description and Replication (TIDieR) Description and content of ECHO and RecoveryMANTRA intervention (i.e. ECHOMANTRA) for adults with AN and their carers (*continued*)

Study protocol	Cardi *et al.* 2017[74]
Item 4: What procedures, activities or processes were used	Patients and carers randomised to the intervention group were able to access the additional resources. The workbooks consisted of seven modules, which were designed to link to key topics in the video library and online groups. The following are examples of these modules: Patient workbook: 1. The impact of the eating disorder on brain and body. 2. Getting a better understanding of the eating disorders. 3. Learning self-compassion. 4. The impact of the eating disorder on your social life. 5. The animal models and the impact of the eating disorder on social relationships. 6. Understanding and managing emotions. 7. Making changes and planning for transition. 8. Managing mealtimes and preventing relapse. Carer groups topics: 1. Eating disorder facts and risk factors. 2. Identifying strengths and resources. 3. Increasing carer resilience. 4. Noticing and managing emotional reactions to the eating disorder. 5. Communicating with compassion. 6. Practising compassionate communication. 7. Planning and facilitating transition. 8. Meal support and preventing relapse. Joint patient and carer groups: 1. Making the most of your support network. 2. Planning techniques for behavioural change. 3. Nurturing personal growth/recovery identity. 4. Nutritional safety following discharge. Online groups Patients and carers were invited to attend eight discussion groups for patients or carer (as relevant) and an additional series of four joint patient–carer groups. These online groups were moderated and facilitated by therapy assistants. The groups provided an opportunity for patients and carers to explore and reflect on a theme illustrated by a video that set the scene. The videos included illustrations of various psychological change strategies such as behavioural experiments, exposure, activity scheduling, cognitive reappraisal, emotional regulation, compassion-focused therapy and if–then planning. The structure and timing of the online facilitated and moderated groups was similar for all three participant groups (patient-only, carer-only and joint patient–carer groups). The protocol for the groups included the following: • Each session lasts 60 minutes. • The use of a recovery-oriented approach with a specific theme for each group. • Scene setting with a video acting to prime group discussion. • The facilitator moderating the discussion using compassionate communication skills informed by motivational interviewing strategies. • The facilitator framed the discussion to underline behaviour change strategies when appropriate. The moderator checked each message against the online facilitated and moderated group rules (e.g. ensuring confidentiality, avoiding unhelpful, triggering or abusive comments). Group sessions were open for participants to join at any time, and participants could take part in as many groups as desired throughout the course of the trial. A transcript of the group was available on the website. Various titles were given to each group topic introduced in the workbook (listed above) to provide variety and encourage participation. Video library The video library comprised of patient and carer 'vodcasts' (brief 1- to 10-minute video podcasts) (n = 134), which map onto the workbooks and relate to recovery experiences, strategies to manage meal anxiety and skills to develop acceptance, self-compassion and improve social functioning. The learning points are emphasised by overlaid images and introductory and summary statements (which include prompts for behaviour change and reflection). The vodcasts illustrate the following behaviour change principles: goal-setting, self-monitoring, utilising social support, and implementation intentions. Within the video library, the following categories of videos were recommended across all chapters of the workbooks and, as recommended, watching prior to the start of the online groups. 1. Psychoeducation and behaviour change strategies: 'Professional tips' n = 51; 'Role plays' n = 19 2. Peer support: 'Recovery stories' n = 54; 'Carer interviews' n = 9 A large component of the recommended videos for carers were those developed in collaboration with SUCCEED, a charity for eating disorders (SUCCEED Foundation). This charity is now closed, but we had permission for these materials to be used in the trial. The SUCCEED videos were role plays with actors demonstrating how supporters could use motivational skills in various typical eating disorder scenarios that can occur in the home setting. These were scripted by a team led by an individual with lived experience and included a role play of 'good enough interactions' which showed high levels of fidelity to motivational interviewing strategies and 'weak interaction' which provided a less-skilled contrast. Topics included within the SUCCEED videos were meal support, family party, restaurant eating, supermarket shopping, overexercising, sibling rivalry, father-daughter relationship, binging-purging, carer respite.

Staff training

Trial assistants were employed with two main roles in the trial (1) research assistants and (2) therapy assistants as online group facilitators/moderators. The research assistants were provided with information relating to the trial administration and facilitation of the study protocol. This included training in the protocol for defining, documenting and reporting SAEs in compliance with the Health Research Authority safety procedures (accessible at: www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/). The research assistants also attended a half-day training course in Good Clinical Practice for non-Clinical Trial of an Investigational Medicinal Product studies.

Training in group facilitation

The therapy assistants facilitated and moderated the online groups. Their responsibilities included planning and setting up the online facilitated and moderated groups and leading the groups for 1 hour in real time with participants. All facilitators were provided with a brief training in the development of the ECHOMANTRA intervention. Before running the online groups, the facilitators and the moderator were required to familiarise themselves with all the materials (published manuals for ECHO[76] and MANTRA[85] and the ECHOMANTRA workbooks and videos). In addition, they received basic training in the MANTRA model and attended five New Maudsley carer workshops (delivered by Jenny Langley), as well as brief practical training and practice in facilitating/moderating the groups. This included introductory materials (PowerPoint slides) on the structure and content to cover during online facilitated and moderated groups and practise role-playing the groups using the online platform. This training was delivered over 2 full days by a representative from the Beat charity. Following this training, basic template scripts were prepared by the study team. The process of running the groups using these template scripts were then piloted with a small group of patient and carer volunteers, who were invited to give feedback on the structure and content before the groups were officially launched as part of the study.

In addition, facilitators received practical training and resources on the motivational interviewing style of communication to be used for facilitation. This training was delivered over 1 day by a member of the Motivational Interviewing Network of Trainers in the form of PowerPoint slides, and group role-plays. New members of the team received copies of all written training materials as well as opportunities to shadow the facilitators/moderators of the online facilitated and moderated groups to start with. In addition, the first few weeks of groups that were delivered by new facilitators/moderators were closely supervised by the trial manager (a clinical psychologist). During the trial, there were five facilitators, four of whom had disclosed lived experience. Additional moderators were recruited (psychology students as part of clinical placements, or volunteer psychology graduates) were trained by the group facilitators and supervisors.

Training in moderation

The role of the moderator was to approve or modify posts to ensure that the group content remained compliant with the ground rules of the group. Moderators were given a copy of the 'ground rules' (which also were shared with participants) and trained in recognising inappropriate content, and in taking appropriate actions in cases of non-compliance to these ground rules [e.g. contacting a participant, general practitioner (GP) or clinical team].

Supervision of facilitation and moderation

Throughout the trial, the facilitators and the moderators received weekly clinical supervision from senior clinicians, including the chief investigator (consultant psychiatrist) and trial manager (clinical psychologist), in the form of feedback on the online facilitated and moderated group transcripts after they had occurred, in terms of adherence to the manualised intervention protocol.

Intervention delivery

The intervention was planned to be delivered to patients and one of their supporters during the transition from intensive hospital treatment (specialist inpatient or intensive day care) back to the community. Participants were able to join the study at any time during their admission up to 4 weeks post discharge; thus, the time at which participants were able to access the study website following admission varied. All participants who signed up were entered into the

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MACRO database, which generated an identification number. This identification number was the participant's username for the website and was the same number for a patient–carer dyad, the only difference being the prefix (i.e. P12345 or C12345).

The intervention was delivered via an online platform that was specifically developed for the study (www.triangle.slam.nhs.uk/). Participants randomised to the intervention group could access all the study resources here, including the workbook, video library and online facilitated and moderated groups. Participants could view or download a PDF copy of the workbook, and they were able to browse all videos in the video library or filter them to videos most relevant to a specific online facilitated and moderated group session. Patients were able to access videos developed more for carers, and carers were able to access the videos developed for patients. Online facilitated and moderated groups were advertised weekly throughout the trial both on the website's online facilitated and moderated groups tab and via e-mails from the research assistants. Participants could reserve a place on an online facilitated and moderated group through the website's booking system. During the online facilitated and moderated groups, participants were anonymised with screen names (their trial identification number) except for the facilitator, moderator and supervisor, who were not anonymised, and their first names were used as their screen names. The transcript of the group could be accessed by all participants who had originally signed up to participate in it.

It was possible for participants who did not sign up to join in with the online facilitated and moderated groups to request a copy of the transcript by e-mailing the research assistants. Since we did not originally set out to assess the impact of this more passive engagement with the groups on the outcome, we did not track or ask participants to report whether/how frequently they read or reread the transcripts. The individual patient/carer online facilitated and moderated groups were scheduled throughout the duration of the trial, starting within a month following recruitment and continuing until 12 months after the last participant had been recruited. Participants (carers and patients) in the ECHOMANTRA study were sent weekly e-mail invitations and reminders for the online facilitated and moderated groups. The series of groups were repeated every 8 weeks. However, the scene setting videos were rotated to provide variation within the same topic.

The original intention was to have the joint carer/patient session delivered to individual dyads via Skype (Microsoft Corporation, Redmond, WA, USA) following the patients' discharge from intensive treatment. However, technical and scheduling difficulties proved to be highly problematic for the initial 32 dyads (only six dyads replied to schedule appointments, and out of these, only four dyads completed the six appointments as per protocol). Therefore, after discussion with the co-applicants and the TSC, from 18 October 2018 (15 months into recruitment), we decided to align the joint sessions with the facilitated and moderated online groups in terms of format and scheduling, that had proved successful. This approach followed the emerging literature suggesting that a multifamily approach was as acceptable and feasible, if not more so, than an individual family approach.[86,87] The timetable for the online facilitated and moderated groups followed a regular cycle of week 1–8 for individual patient and carer group and week 1–5 for joint groups. Participants could join at any time within the cycle, and they were invited to repeat groups as often as wanted. Attendance at the groups were recorded by the website. The individual groups were scheduled in the evening, typically for 1 hour, between 7–8 and 8–9 p.m.

Completion of follow-ups

The main follow-up measures (primary and secondary outcomes) were collected at 12 and 18 months post randomisation. These were generally collected via the platform, although a flexible approach was employed to ensure retention and to minimise dropout rates at these key assessment intervals. For example, the research assistants would accommodate whichever method of completion was most convenient for the participants. This included post or telephone support to complete the measures via the platform, or in a minority of cases, the researcher would administer the questionnaire via telephone and note down the participants' responses. Further efforts were made to ensure retention. For example, additional measures of depression, anxiety and stress symptoms,[88] weight, and social connection were administered to participants via the study platform monthly, with the goal of encouraging participants to maintain their involvement in the study and to improve data modelling. Upon completion of these, both patient and carer participants were able to access feedback charts and use these to self-monitor their progress over time.

Participants were also consulted on their preferred method of contact during the study and could opt-in to receive e-mails, telephone calls, texts or all forms of communication. Throughout the study, the research assistants maintained regular contact with the participants using these preferred methods to encourage engagement with the study. For example, monthly newsletters were sent via e-mail, and personalised e-mails were sent at baseline and at 3, 6, 9, 12 and 18 months to remind participants about the online questionnaires and to thank them for their contributions with voucher reimbursement. Participants were also sent birthday texts and Christmas cards.

Remuneration

Participants were offered the full reimbursement following completion of the study (£60 for patients and £60 for carers). However, based on feedback from participants and our TSC, we decided to find ways to reimburse participants more frequently as a method of improving retention rates. In most cases, we were able to reimburse participants every 3 months, immediately after completing their follow-up questionnaires online using shopping vouchers.

Adverse event monitoring

Serious adverse events were classified according to the Health Research Authority definition, 'any untoward occurrence that: (a) results in death (b) is life-threatening (c) requires hospitalisation or prolongation of existing hospitalisation (d) results in persistent or significant disability or incapacity (e) consists of a congenital anomaly or birth defect' (www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/). Weight loss was defined as a psychological health event and regarded as an expected marker of relapse following inpatient care.

Information on SAEs was collected over the 18 months following consent into the study. This information could be reported by participants themselves, their carers or the clinical team. Participating sites were requested to inform the study team of SAEs recorded while the participant was in their care (i.e. while they remained on the inpatient unit/day-care programme). The research assistants also closely monitored participants' questionnaire responses for self-reported adverse events (AEs), such as a re-admission to hospital, or other signs of relapse, including self-reported weight loss and distress. E-mails from patients, carers and clinical staff from participating sites were also checked daily for information on the well-being of specific participants. The research assistants followed up events raising safety concerns with the participants' clinical team, or GP, in cases where the participants had been discharged from their care. All AEs were reviewed by the chief investigator (consultant psychiatrist) and the DMC, including an independent statistician and two psychiatrists, during annual or biannual meetings. For events resulting in death, the DMC were unblinded to the participant' condition allocation and were asked to assess whether these events were likely to be related or unrelated to their trial participation.

Evaluation of treatment fidelity

With participants' consent, the online group session transcripts were saved for training, supervision, assessment of fidelity of the intervention and qualitative analysis. Two experienced clinical practitioners, including the chief investigator (consultant psychiatrist) and the trial manager (clinical psychologist), undertook weekly supervision of the online group transcripts. They were responsible for assessing the extent to which the group facilitators adhered to the motivational interviewing style of communication, guided by the Motivational Interviewing Treatment Integrity (MITI) competency scale, and the manualised intervention protocol.

Summary of changes to the project protocol

In the initial stages of the study, the protocol was disseminated to local principal investigators and research and development staff at each recruitment site via e-mail. Additionally, staff from all sites that had signed up at that time (n = 19) were invited to a study conference meeting at the Institute of Psychiatry, where the protocol was presented by

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the chief investigator and the trial manager. The early dissemination of the protocol generated active dialogue between the research hub and the clinical sites about issues relevant to eligibility and recruitment within their clinical practice.

Table 3 presents a summary of the key changes to the project protocol which were made during the trial, following consultation with site staff, the TSC and DMEC, and after obtaining the necessary approvals from the REC. For a list of all study amendments and dates when these approvals were obtained, see *Appendix 1*, *Table 40*.

Key change to intervention delivery

The joint guidance for patient–carer dyads was delivered via facilitated and moderated online groups involving multiple patient–carer dyads, instead of via Skype sessions between a single patient–carer dyad and a mentor.

Key changes to data collection

- Patients self-reported clinical data (e.g. changes in medication and therapy) where possible to reduce burden on clinical teams.
- Additional qualitative data were collected from subsamples of patients and carers on the experience of transition, the experience of the ECHOMANTRA intervention, and the impact of COVID-19 on the lives of patients and carers in the study.

TABLE 3 Changes to eligibility criteria for patient participants

Inclusion criteria	Changes applied to inclusion criteria during the trial
a. Patient aged 16 or over	Changed from minimum age 17, effective from 6 December 2018, 17 months into recruitment
b. DSM-V diagnosis of AN with a BMI of ≤ 18.5 kg/m^2 or atypical AN on admission to the inpatient/day-care unit	Changed from a diagnosis of AN only on 27 March 2017, ahead of recruitment Defined the time at which the BMI criteria apply on 29 May 2018 (i.e. 10 months into recruitment)
c. Carer willing to participate (we will use a broad definition of 'carer' to include family and/or friends willing and able to provide some aftercare support)	Unchanged
d. Informed consent signed while patient is admitted into hospital up to 4 weeks after discharge	Changed from consent within 2 months of admission, effective from 27 December 2018, 17 months into recruitment
e. Participants able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and the internet to use the study's website	Unchanged
Exclusion criteria	
a. The patient is not admitted to hospital or attending day care for a minimum of 3 days/week when they are consented in the study	Changed from attending for a minimum of 4 days/week, effective from 27 December 2018, 17 months into recruitment
b. The patient has an insufficient knowledge of English	Unchanged
c. The patient has severe mental or chronic physical illness needing treatment in its own right (e.g. psychosis, diabetes mellitus, cystic fibrosis etc.)	Unchanged
d. The patient is pregnant	Unchanged
e. The patient–carer dyad has previously received treatments involving the ECHOMANTRA materials (e.g. as part of the iMANTRA trial or the CASIS study)	Unchanged
f. Baseline measures have not been completed by the dyad	

DSM-V, *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition.
Note
The original eligibility criteria were first documented in the protocol paper.[74]

Measures

Patient measures

- Patient demographic and clinical data: date of birth; sex; whether recruited from inpatient or day care; date of admission; ethnicity; highest level of education completed; marital status; number of daughters and sons; lifetime diagnoses of depression, anxiety, OCD, attention deficit hyperactivity disorder (ADHD), ASD, panic disorder, phobia, other disorders; number of first-degree relatives (parents, siblings, children) who have been diagnosed with ASDs, eating disorders or other psychological problem or mental illness; number of second-degree relatives (grandparents, grandchildren, aunts, uncles) who have been diagnosed with eating disorders; lifetime treatment under the Mental Health Act (MHA) and number of occasions; lifetime treatment under a Community Treatment Order (CTO); duration of eating disorder in years; current weight and height; lowest weight since diagnosis; and highest weight in lifetime.
- Patient eating disorder symptoms – Eating Disorder Examination Questionnaire (EDE-Q[89]): the EDE-Q is a 36-item self-report measure of eating disorder symptoms (dietary restraint, eating concerns, weight concerns, shape concerns) in the past 28 days, on a scale ranging from no days (0) to every day (6). In the main analysis, the global score was used as a marker of eating-disorder-symptom severity. A higher score indicates greater frequency of symptoms.
- Patient BMI: BMI is calculated as Weight (kg)/Height (m^2). This was primarily reported by patients. Clinicians at participating centres were also asked to provide weight and height at baseline from clinical records.
- Depression, anxiety and stress symptoms – Depression Anxiety Stress Scale-21 (DASS-21[88]). The DASS-21 is a 21-item self-report measure of depression, anxiety and stress symptoms in the past week, on a scale ranging from 0 ('did not apply to me at all') to 4 ('applied to me very much, or most of the time'). A higher score indicates greater frequency of symptoms.
- Patient work and social adjustment – Work and Social Adjustment Scale (WSAS[90]). The WSAS is a five-item measure of functional impairment. In this trial, the WSAS was used to assess the impact of the eating disorder on the ability to function in the areas of work, home management, social leisure activities, private leisure activities and personal relationships. A higher score indicates greater impairment.
- Patient social functioning – Strengths and Difficulties Questionnaire (SDQ[91]). The SDQ is a 25-item measure of psychological attributes related to the areas of emotional symptoms, conduct problems, hyperactivity/inattentiveness, peer relationship problems and prosocial behaviour (in the last 6 months). In this trial, the carer-informant version was administered as a measure of social functioning in patients. A total score was calculated using four subscales (excluding prosocial behaviour). For the total score, a higher score indicates greater problems.
- Patient autistic symptoms – Autism Spectrum Quotient (AQ-10[92]). The AQ-10 is a 10-item self-report measure of autistic symptoms, rated on a scale from definitely agree to definitely disagree. The total score is based on all items. A score > 6 indicates high levels of autistic symptoms.
- Patient obsessive–compulsive symptoms – Obsessive Compulsive Inventory – Revised (OCI-R[93]). The OCI-R is an 18-item self-report measure of obsessive–compulsive symptoms in the past month. The measure covers six dimensions, including checking, washing, ordering, hoarding, obsessing and neutralising. Items are rated on a scale from 0 ('not at all') to 4 ('extremely'). A score > 21 indicates high levels of obsessive–compulsive symptoms.
- Importance to change (motivation to change – motivational rulers) reported by patients. A single item, 'How important is it for you to change? What score would you give yourself out of 10?', was rated on a scale from 1 ('not at all important') to 10 ('extremely important').
- Ability to change (motivation to change – motivational rulers) reported by patients. A single item, 'How confident are you in your ability to change? What score would you give yourself out of 10?', is rated on a scale from 1 ('not at all confident') to 10 ('extremely confident').

Patient health economics measures

- Health-related quality of life – EQ-5D.[94] The ED-5D is a five-item, self-report measure of quality of life across five domains, including mobility, self-care, usual activities, pain/discomfort, anxiety/depression. The three-level version rates each domain from 1 (no problem), 2 (moderate problem) or 3 (severe problem). Thus, a higher score indicates poorer quality of life in each domain. The scale also includes a visual analogue scale, which indicates the general

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health status from 0 ('worst health imaginable') to 100 ('best health imaginable'). The utility values generated from the EQ-5D can be transformed into quality-adjusted life-years (QALYs).
- Cost-effectiveness – a modified version of the Client Service Receipt Inventory (CSRI).[95] The CSRI collects retrospective information about use of services, service-related issues and other impacts such as time out of employment. In this study, the duration used was 3 consecutive months prior to completing the inventory.

Further details about the health economic assessment measures used in this trial and the associated outcomes can be found in *Chapter 4*.

Carer measures

- Demographic and clinical data. Date of birth, sex, nature of relationship to participant (e.g. parent), current employment status, highest level of education completed, whether English was first spoken language, ethnicity, marital status, number of daughters, number of sons.
- Caregiving skills: Caregiver Skills (CASK[96]). The CASK scale is a 27-item measure of caregiving attitudes and behaviours for dealing with eating disorder symptoms.
- Depression, anxiety and stress symptoms – DASS-21.[88] As described in the section above on patient baseline measures.

The timing of the administration of the measures above is summarised in *Table 4*.

Primary outcome measure

The primary outcome of the TRIANGLE trial was patient DASS-21 total scores at 12 months post randomisation.

Secondary outcome measures for patients

- Depression, anxiety and stress symptoms on the DASS-21[88] at 18 months post randomisation.
- BMI at 12 and 18 months post randomisation.
- Eating disorder symptoms on the EDE-Q[89] at 12 and 18 months post randomisation.
- Work and social adjustment on the WSAS[90] at 12 and 18 months post randomisation.
- Importance to change (motivation to change – motivational rulers) reported by patients at 12 and 18 months post randomisation.
- Ability to change (motivation to change – motivational rulers) reported by patients at 12 and 18 months post randomisation.
- Social functioning total scores as reported by carers on the SDQ[91] at 12 months post randomisation.
- Number of days spent in hospital (at 12 and 18 months post randomisation) – Hospital Episode Statistics (not obtained from NHS Digital due to poor data quality).
- Number of days spent in hospital (in the past 3 months) self-reported by patients in the CSRI as a substitute for Hospital Episode Statistics data[95] at 12 months.
- Other health service use, productivity losses and out-of-pocket expenses at 12 months as collected using the CSRI.
- Quality of life measured using the EuroQol-5 Domains, three-level version (EQ-5D-3L) instrument[94] at 12 months post randomisation.
- Intervention cost-effectiveness as measured in terms of cost per QALY gained at 12 months from both a health system and wider societal perspective.

Secondary outcome measures for carers

- Depression, anxiety and stress symptoms on the DASS-21 at 12 and 18 months post randomisation.
- Caregiving skills on the CASK[96] scale at 12 and 18 months post randomisation.

TABLE 4 Trial assessment schedule

	Time point (month)						
Variable	**Baseline**	**3**	**6**	**9**	**12**	**18**	**1–18**
Patient measures							
Patient demographics	X						
Patient BMI	X	X	X	X	X	X	X
Patient psychological medical history	X						
Social support	X						
CSRI	X				X		
EDE-Q	X	X	X	X	X	X	
DASS-21	X	X	X	X	X	X	X
WSAS	X		X		X	X	
Motivational rulers	X	X	X		X	X	
AQ-10	X						
OCI-R	X						
EQ-5D	X				X		
SDQ (carer-reported)	X				X		
SAEs							X
Psychological concomitant medications	X						X
Carer measures							
Carer demographics	X						
Carer patient relationship	X						
DASS-21	X	X	X	X	X	X	X
CASK	X		X		X	X	
SAEs							X

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Data management

Most of the study data from participants were collected on the TRIANGLE study website (www.triangle.slam.nhs.uk/); however, participants were offered the alternative to complete the measures on paper forms. Any hard copies of source data were stored in locked filing cabinets in the research office at King's College London and had restricted access. The research assistants and data entry assistants manually entered most of the data into an online database for clinical trials (MACRO), hosted by a dedicated server at King's College London and managed by the King's Clinical Trials Unit. The research assistants conducted a manual data cleaning process on 100% of the data for all participants. The statistician performed separate systematic data checks on 100% of the data for all participants. The trial statistician received blinded data extracts from MACRO and the randomisation system throughout the trial to complete systematic data checks and prepare reports for the DMC meetings. The CSRI, EQ-5D and social support forms were transferred to the health economist as raw data extracts from the TRIANGLE study website. The health economist cleaned these data and raised queries with the research assistants to resolve.

Power calculation and sample size

The a priori sample size calculation of 380 dyads was based on wishing to detect a clinically significant improvement of Cohen's d = 0.40 in the primary outcome (DASS-21) at 12 months, in the ECHOMANTRA + TAU arm compared to the TAU only arm, with 90% power, using a two-tailed t-test, at a significance level of a < 0.05, and allowing for attrition rate of 30% based on similar attrition rates observed in previous studies (e.g. 37% in patients and 41% in carers at 12 months; 19). The effect size was estimated based on previous research and our assessment of clinically significant change. A previous trial testing an internet-based intervention for patients (iMANTRA) achieved an effect size of d = 0.64 on DASS-21 at 12 months.[65] In addition, in the CASIS trial, we tested a carer intervention targeting parents and partners only, and found an effect on patient DASS-21 of d = 0.17 at 12 months[6] and d = 0.25 at 24 months.[73] Therefore, the effect size of d = 0.40 for the TRIANGLE trial was a conservative estimate of effect size we expected to achieve with the combined ECHOMANTRA intervention. The DASS profile sheet quotes the following reference ranges to interpret level of distress from the total score: moderate 43–59 points, severe 62–79 points, extremely severe 82 + points. Based on the CASIS study [mean = 62, standard deviation (SD) = 31 in TAU arm at 12 months, n = 57], we expected our target population to be in the lower end of the severe range of distress at 12 months under standard treatment. An improvement of d = 0.40 amounts to a reduction of 11 points (based on a SD = 28; 19) and would, therefore, shift the distress score into the middle of the moderate range. This would, therefore, be considered clinically significant.

Statistical analyses

A SAP was developed during the study and agreed by the TMG and TSC before database lock (internal document). All statistical analyses, unless otherwise stated in the next chapter, or in *Appendix 2*, followed this SAP. Analyses were conducted by the trial statistician and checked by the senior statistician. Here we provide a summary of the descriptive and inferential approaches that were employed to address the primary objective and first three secondary objectives of the TRIANGLE study.

We generated descriptive summaries of baseline variables overall and by trial arm to describe the trial sample and confirm that randomisation operated as planned. We also constructed descriptive summaries of process variables such as the number of times a patient or carer accessed an online forum session to describe the patient or carer experience of the ECHOMANTRA add-on treatment. Raw outcome data summaries were also tabulated over time and by trial arm, and both proportions describing AEs and concomitant medications were provided. To formally assess clinical effectiveness, post-randomisation differences in primary and secondary outcomes between the trial arms were estimated. In the first instance, all outcomes were analysed on an intention-to-treat basis, that is, we analysed all those with data in groups as randomised irrespective of treatment received. For continuous outcome variables (DASS-21 patient or carer, BMI, EDE-Q, WSAS, importance to change, ability to change, SDQ social functioning, CASK), a linear mixed model was used to estimate the trial arm differences. These analysis models contained the respective outcome

variable as the dependent variable and baseline values of the variable, trial arm and randomisation stratifier illness severity as (fixed) explanatory variables. The models also contained a site-varying random intercept to condition on the second randomisation stratifier site (classed into 11 broad categories; see below). The variable 'inpatient days spent in hospital during the 3 months prior to the 12-months follow-up date' was a count variable and modelled by a negative binomial model to allow for overdispersion. In this analysis, model site featured as a fixed effect (10 dummy code variables) rather than a random effect due to lack of site variability leading to non-convergence for the random-effects model.

We empirically investigated whether baseline variables were predictive of missingness of the primary outcome variable (patient DASS at 12 months). This was done by first generating a binary missingness indicator for the primary outcome variable (0 = not missing, 1 = missing) and regressing this on each baseline variable in-turn, together with pre-planned covariates baseline DASS-21 scores, trial arm and minimisation factors illness severity and recruitment site. Here, logistic mixed-effects modelling was utilised with the original recruitment site added as a random effect to account for site variability (N = 31 sites). All other covariates were included as fixed effects. We also investigated whether non-adherence with the add-on treatment predicted missing primary outcome values in the ECHOMANTRA arm using a chi-squared test. For this purpose, adherence to the study intervention was pre-defined in the SAP as both the patient and carer attending at least four online forum group sessions and was captured within the ECHOMANTRA arm only. We found a considerable amount of attrition in the primary outcome (see next chapter) and detected a positive association between non-adherence with ECHOMANTRA and later dropout from data collection. It was therefore important to allow for such a missing at random (MAR) missing value generating process in the formal inferential analyses. We achieved this by using MI via the multivariate imputation via chained equation (MICE).[97]

Multiple imputation (MI) consists of two steps: (1) repeatedly imputing missing values using an imputation model that reflects the MAR mechanism and (2) analysing each imputed data set with an appropriate analysis model and combining results using specific rules (so-called Rubin's rules). All variables of the analysis model need to be included in the imputation model for MI to provide valid inferences under MAR, but the imputation model can also be more general (e.g. include extra predictors). In our context, MI allowed us to accommodate non-adherence with ECHOMANTRA predicting dropout by including the binary adherence variable in the imputation model but not in the analysis model. We thus use MI to generate inferences that are valid under our detected MAR missing data generating process and so correct for missing data biases. Specifically, we used the following procedures: the analysis models of the two-stage procedure were those specified earlier. The imputation models used chained equations to generate multivariate imputation models for all the variables contained in the respective analysis model (i.e. baseline, trial arm, illness severity and site) plus further variables that were thought to drive missingness (one baseline variable 'Ever treated under the MHA followed by a CTO?' detected empirically, non-adherence with ECHOMANTRA and further measures of the respective dependent variable at 9, 12 or 18 months). During the chained equations imputations missing values in continuous variables were imputed from a regression model, except for importance to change, ability to change and hospital days which were imputed using predictive mean matching (based on 10 nearest neighbours) to ensure that imputed values lay within the range of the respective scale. The binary MHA/CTO and non-adherence variables were imputed from a logistic regression. Sites were included in the imputation models as (fixed) dummy variables. To avoid overparameterisation, the original 31 sites were merged into 11 broad site categories such that each category contained at least five post-randomisation outcome observations. We generated 100 imputations for each outcome analysis.

We carried out several sensitivity analyses for the primary outcome DASS-21:

- Efficacy of the intervention: we constructed a binary measure of receipt of add-on treatment (both the patient and the carer attending at least four online forum sessions) and used instrumental variables approach to estimate the effect of receipt of the intervention (randomisation acts as an instrument for the endogenous variable treatment receipt). The efficacy estimand estimated is the complier-average causal effect (CACE).
- Not meeting the original eligibility criteria: we checked how the results vary if we considered only those participants who met the eligibility criteria of AN when they were randomised.
- Impact of COVID: the trial intervention is an online intervention, and data collection from participants was also predominantly conducted online. As the intervention provision was not expected to be affected by the COVID crisis and the population covered by the desired treatment effect estimand includes dyads recruited during the COVID

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period, we did not change the main analyses. To understand the impact of COVID, we provided baseline descriptive statistics split by those recruited before and after 11 March 2020 by arm and overall. We also constructed 12-month outcome descriptive statistics split by visit date before and after 11 March 2020 by arm and overall. Finally, we carried out a sensitivity analysis to consider the effect of COVID on the treatment effect by repeating the primary analyses for the subset of patient data collected before 11 March 2020.

All statistical analyses were carried out in Stata (StataCorp LP, College Station, TX, USA, Stata data analysis and statistical Software. Special Edition Release. 2007;**10**:733).

Chapter 3 Findings from the Transition Care In Anorexia Nervosa through Guidance Online from Peer and Carer Expertise study

Introduction

This chapter presents the clinical findings from the TRIANGLE RCT. The trial protocol was published in 2017.[74] The statistical methods used are summarised in *Chapter 2*. Analyses followed a detailed SAP which had been developed by the statisticians in collaboration with the TMG and approved by the TSC prior to database lock. Any instances in which the analyses or reporting have deviated from the SAP are outlined in *Appendix 3*.

The trial finished recruiting participants on 3 July 2020, and the last randomisation of a patient–carer dyad took place on 20 July 2020, with a total of 371 dyads randomised. Database lock of the main MACRO databases took place on 8 July 2022. The final data extracted from MACRO were dated 8 July 2022. The statistical analyses were conducted by the trial statistician (JL) and reviewed by the senior statistician (SL). The final statistical report was signed off by the statisticians on 21 November 2022. Here we follow the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.[98]

Recruitment

Figure 4 illustrates the cumulative recruitment of dyads over time, with numbers for planned recruitment (blue) plotted against the numbers for actual recruitment (red). We met with the funder to discuss recruitment in December 2017, and the expected recruitment rate was subsequently readjusted. Final recruitment fell slightly below the intended sample size of 380, with a final total of 371 dyads randomised into the study.

The CONSORT diagram shown in *Figure 5* illustrates that 960 patients were screened for eligibility in the study, of which 371 were randomised along with their carer into the study sample (TAU + ECHOMANTRA = 185, TAU = 186). One patient–carer dyad randomised in error within the ECHOMANTRA was withdrawn immediately following randomisation. This dyad did not provide baseline or outcome data and did not receive any intervention. Data collection

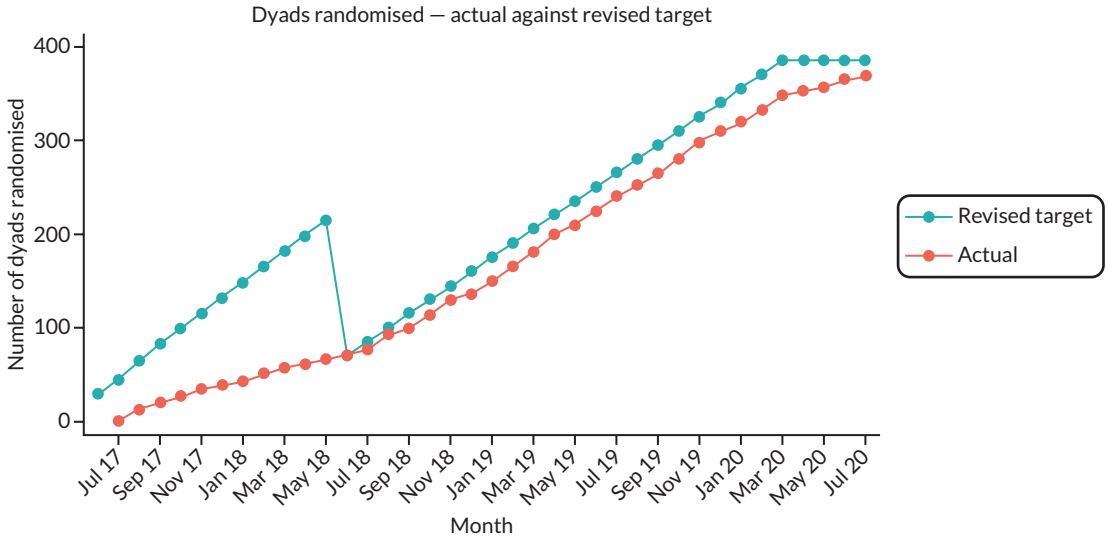

FIGURE 4 Cumulative recruitment over time – actual vs. target.

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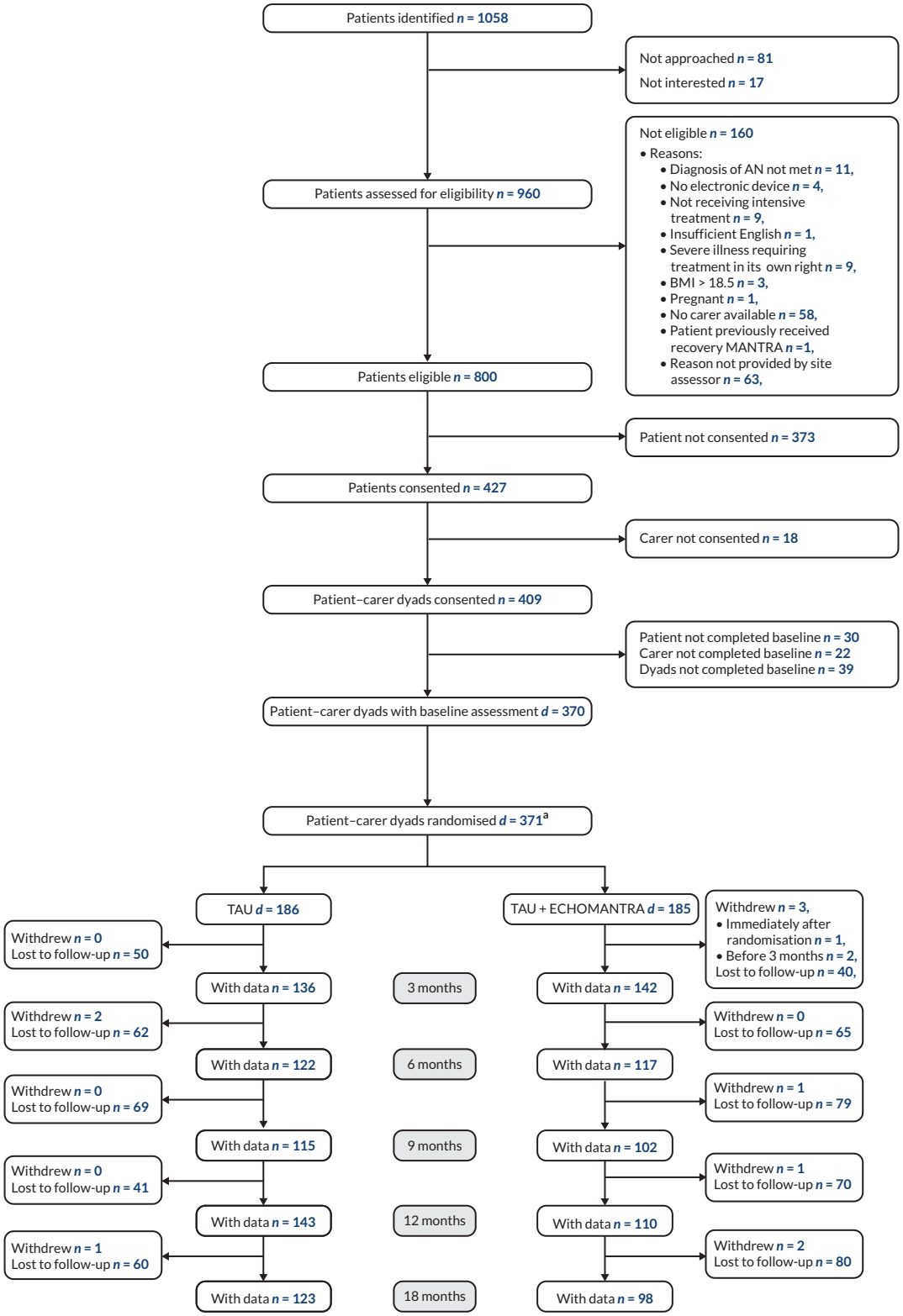

FIGURE 5 Consolidated Standards of Reporting Trials diagram. a, The randomised trial sample included one patient who had not completed baseline assessments nor consented to trial participation and thus this patient and their carer was randomised in error. This patient and their carer were therefore withdrawn from the study immediately after randomisation, before any treatment commenced. The participant has been noted as an immediate withdrawal within their respective randomised arm and is not included within any analyses due to absent data. Additionally, the trial sample includes three dyads who were randomised despite patients not meeting the BMI inclusion criterion. To maintain randomisation, these are included as part of the intention-to-treat analysis but subsequently removed from the trial sample as part of a sensitivity analysis.

was prioritised for the primary outcome time point (12 months) to ensure maximum possible coverage. At 12 months, the primary outcome patient DASS scores was observed for 253 participants (ECHOMANTRA = 110, TAU = 143).

The numbers of individuals are represented by *n* and the number of dyads by d. Any *n* listed within the diagram after patient–carer dyad randomisation specifically reflects patients, reflecting the availability of the primary patient outcome.

Table 5 illustrates withdrawals by 12 months. The numbers lost to follow-up reflect patients for whom no primary data were available despite no formal withdrawal. The amount of missingness was higher within the ECHOMANTRA arm (*N* = 87) compared to the TAU arm (*N* = 63). The following reasons were provided for withdrawal from the group (*N* = 3) categorised as 'other':

- The patient found TRIANGLE too demanding.
- The patient wanted to move on from eating disorder reminders.
- Issues with the time commitment.

Study population

Table 6 shows the BMI profile of the three participants who presented with the features of atypical AN criterion (BMI > 18.5) whereby the diagnosis is made considering weight suppression rather than underweight categorisation among other features.

Sites

Patients were recruited from specialised eating disorder day patient and inpatient services (independent and NHS) from across England and Scotland. A total of 31 sites took part in this study. The randomised dyads split by site and trial arm are shown in *Table 7*.

TABLE 5 Reasons for missing data of the primary end point (DASS at 12 months)

Reason for missing data	TAU *N* (%)	TAU + ECHOMANTRA *N* (%)	Overall *N* (%)
Patient no longer wishes for data to be collected	0 (0.0)	2 (2.3)	2 (1.3)
Lost to follow-up	60 (95.2)	80 (92.0)	140 (93.3)
Death[a]	3 (4.8)	2 (2.3)	5 (3.3)
Other	0 (0.0)	3 (3.4)	3 (2.0)

a One additional participant was also reported withdrawn due to death in the trial database, but this death occurred subsequent to all data collection (~24 months post randomisation) and so is not listed as a withdrawal within this report.

TABLE 6 Descriptive table comparing the baseline weight profile from patients who were randomised, including those that met the atypical AN diagnostic category due to not fitting the BMI eligibility criterion (BMI < 18.5)

Baseline weight variable	BMI ≤ 18.5 *N* = 367 Mean (SD)	BMI > 18.5 *N* = 3 Mean (SD)	Overall *N* = 370 Mean (SD)
Highest weight ever (kg)	57.8 (11.7) [34]	68.2 (13.0) [0]	57.9 (11.7) [34]
Lowest weight since eating disorder began (kg)	36.6 (5.9) [14]	49.7 (9.7) [0]	36.7 (6.0) [14]
Clinician-reported weight (kg)	39.7 (6.1) [26]	54.4 (7.3) [0]	39.9 (6.2) [26]
Patient-reported weight (kg)	43.5 (6.6) [11]	54.2 (7.6) [0]	43.6 (6.7) [11]
Weight suppression (kg) – Median (IQR)	12.0 (7.4–18.1) [39]	17.0 (3.0–21.9) [0]	12.0 (7.3–18.1) [39]

IQR, interquartile range.
Note
Square parentheses represent number of missing entries.

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TABLE 7 Randomisation by trial arm and study site

Site	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 185 *N* (%)	Overall *N* = 371 *N* (%)
1. South London and Maudsley	13 (7.0)	11 (6.0)	24 (6.5)
2. Cheshire and Wirral	2 (1.1)	3 (1.6)	5 (1.3)
3. South Staffordshire	5 (2.7)	5 (2.7)	10 (2.7)
4. Avon and Wiltshire	8 (4.3)	8 (4.3)	16 (4.3)
5. Dorset	5 (2.7)	4 (2.2)	9 (2.4)
6. Central and NW London	7 (3.8)	6 (3.2)	13 (3.5)
7. Barnet, Enfield and Haringey	13 (7.0)	12 (6.5)	25 (6.7)
8. Leicestershire	13 (7.0)	12 (6.5)	25 (6.7)
9. Northumberland, Tyne and Wear	7 (3.8)	5 (2.7)	12 (3.2)
10. Royal Cornhill	2 (1.1)	1 (0.5)	3 (0.8)
11. SE Scotland	1 (0.5)	1 (0.5)	2 (0.5)
12. SW London and St Georges	17 (9.1)	16 (8.6)	33 (8.9)
13. North Essex	3 (1.6)	4 (2.2)	7 (1.9)
14. 2gether	2 (1.1)	1 (0.5)	3 (0.8)
15. Berkshire	10 (5.4)	10 (5.4)	20 (5.4)
16. Oxford	9 (4.8)	9 (4.9)	18 (4.9)
17. Ellern Mede Centre	3 (1.6)	4 (2.2)	7 (1.9)
18. Priory Roehampton	4 (2.2)	4 (2.2)	8 (2.2)
19. Priory Southampton	6 (3.2)	6 (3.2)	12 (3.2)
20. Priory Altrincham	11 (5.9)	11 (6.0)	22 (5.9)
22. Priory Cheadle	11 (5.9)	11 (6.0)	22 (5.9)
23. Surrey Borders	4 (2.2)	5 (2.7)	9 (2.4)
24. Devon	5 (2.7)	5 (2.7)	10 (2.7)
25. Ellern Mede Barnet	2 (1.1)	3 (1.6)	5 (1.3)
26. Priory Hayes Grove	3 (1.6)	5 (2.7)	8 (2.2)
27. Tees, Esk and Wear	5 (2.7)	5 (2.7)	10 (2.7)
28. Community	4 (2.2)	5 (2.7)	9 (2.4)
29. Cambridgeshire and Peterborough	6 (3.2)	6 (3.2)	12 (3.2)
30. New Market	2 (1.1)	2 (1.1)	4 (1.1)
31. Cardinal Clinic	1 (0.5)	2 (1.1)	3 (0.8)
32. Orri ED Clinic	2 (1.1)	3 (1.6)	5 (1.3)

Note
Site 21 (Priory Bristol) is not included within sites listed due to this site dropping out prior to study start due to no principal investigator being available.

Patients

Table 8 displays randomised dyads split by illness severity.

Tables 7 and *8* show that both the minimisation factors (site and illness severity) are similar across both trial arms. *Table 9* provides an overview of baseline variables for patients who were included within the trial. Patients were predominantly female, white, single, aged 25–26 years, with a median illness duration of 5 years. A quarter of the patients had an illness duration of < 3 years (i.e. fulfilling FREED early intervention criteria; 104). Most patients (76%) were recruited from inpatient care, and 19% were currently admitted under the MHA (and 16% had previous admissions, with a median of 2, under the MHA). Patient self-reported comorbidity included depression (62%), anxiety (59%), OCD (16%), ASD (5%) and ADHD (2%). The median score on the AQ-10 (96) was 4, interquartile range (IQR) (3–6) with 16.5% scoring above the cut-off of 6. The median score on the Obsessive-Compulsive Disorder Inventory (OCI-R; 97) was 24, IQR (16–37) with 59.7% above the cut-off of 21. Patient characteristics were comparable across the trial arms.

Carers

Table 10 provides an overview of baseline variables for carers. Most carers were mothers aged 50 years although 30% were male and 17% were partners. Most carers were white, married, spoke English as their first language, were university educated and in paid employment. Carer characteristics were also comparable across trial arms.

ECHOMANTRA add-on treatment experience

There were no carer changes in our study. Thus, ECHOMANTRA was offered only to the dyads who were originally randomised to the trial. Adherence to the ECHOMANTRA intervention was defined as both the patient and carer attending at least four online forum group sessions. Based on this criterion, a high proportion (80.4%) of non-adherence was observed. *Figure 6* provides a graphical summary of the number of online forum sessions attended by patients and carers within the intervention arm. This shows that the majority of both patients and carers attended no online group forum sessions throughout the duration of the intervention. As part of the intervention, several resources in addition to the online groups were made available to dyads within the intervention arm. These included DVDs, psychoeducational vodcasts, and recovery vodcasts, and a written toolkit. Due to a technical fault within the TRIANGLE website, it was not possible to access data relating to individual downloading of these materials. Patient-reported feedback about the usage of these materials is reported in *Chapter 5*.

Description of outcome data

Patients

A total of 117 participants (31.6%) were missing DASS-21 data at 12 months [TAU = 43 (23.1%), ECHOMANTRA = 74 (40.2%)]. Summaries of the raw, unadjusted average values for each of the primary and secondary patient outcome measures across all available time points are shown in *Table 11*. Profile plots for the primary outcome are shown in *Figure 7*. The profile plots for each of the remaining primary and secondary patient outcome measures across all available time points are shown in *Report Supplementary Material 1*, *Figure 1*.

The outcome measures at baseline show the usual profile of those admitted for inpatient care. There were high levels of distress (DASS), eating psychopathology (EDEQ) and a low BMI. Patients also showed an impairment in their work and

TABLE 8 Randomisation by trial arm and illness severity

Severity	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 185 *N* (%)	Overall *N* = 371 *N* (%)
BMI < 15	72 (38.7)	71 (38.4)	143 (38.5)
BMI ≥ 15	114 (61.3)	114 (61.6)	228 (61.5)

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TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Age			
Mean (SD)	25.1 (8.4)	25.8 (9.4)	25.4 (8.9)
Median (IQR)	22.9 (19.4–27.6)	22.4 (19.6–28.9)	22.5 (19.5–27.8)
Sex			
Male	11 (5.9)	13 (7.1)	24 (6.5)
Female	175 (94.1)	171 (92.9)	346 (93.5)
Ethnicity			
Asian	4 (2.2)	1 (0.5)	5 (1.4)
Black	2 (1.1)	0 (0.0)	2 (0.5)
White	176 (94.6)	174 (94.6)	350 (94.6)
Mixed	4 (2.2)	8 (4.4)	12 (3.2)
Missing	0 (0.0)	1 (0.5)	1 (0.3)
Highest completed education			
No qualifications	5 (2.7)	7 (3.8)	12 (3.2)
O Level/GCSE	34 (18.3)	24 (13.0)	58 (15.7)
A Level/NVQ	50 (26.9)	67 (36.4)	117 (31.6)
Diploma/BTEC	19 (10.2)	23 (12.5)	42 (11.4)
University degree	48 (25.8)	47 (25.5)	95 (25.7)
Postgraduate degree	23 (12.4)	16 (8.7)	39 (10.5)
Other	6 (3.2)	0 (0.0)	6 (1.6)
Missing	1 (0.5)	0 (0.0)	1 (0.3)
Marital status			
Married	14 (7.5)	21 (11.4)	35 (9.5)
In a relationship and cohabiting	15 (8.1)	15 (8.2)	30 (8.1)
In a relationship and not cohabiting	14 (7.5)	11 (6.0)	25 (6.8)
Single	139 (74.7)	133 (72.3)	272 (73.5)

TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall (*continued*)

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Divorced	0 (0.0)	2 (1.1)	2 (0.5)
Separated	2 (1.1)	2 (1.1)	4 (1.1)
Widowed	1 (0.5)	0 (0.0)	1 (0.3)
Missing	1 (0.5)	0 (0.0)	1 (0.3)
Patient recruited while.			
Being admitted for inpatient care	143 (76.9)	140 (76.1)	283 (76.5)
Attending day care for at least 3 days per week	43 (23.1)	44 (23.9)	87 (23.5)
Number of daughters			
0	174 (93.6)	169 (91.9)	343 (92.7)
1	6 (3.2)	11 (6.0)	17 (4.6)
2	5 (2.7)	2 (1.1)	7 (1.9)
Missing	1 (0.5)	2 (1.1)	3 (0.8)
Number of sons			
0	176 (94.6)	169 (91.9)	345 (93.2)
1	6 (3.2)	9 (4.9)	15 (4.1)
2	2 (1.1)	2 (1.1)	4 (1.1)
3	1 (0.5)	2 (1.1)	3 (0.8)
Missing	1 (0.5)	2 (1.1)	3 (0.8)
Height (cm) – mean (SD)	165.4 (7.1) [1]	165.9 (7.7)	165.6 (7.4) [1]
Clinician-reported weight at admission (kg) – mean (SD)	40.1 (6.1) [11]	39.6 (6.3) [15]	39.9 (6.2) [26]
Participant-reported weight (kg) – mean (SD)	43.4 (6.4) [6]	43.8 (6.9) [5]	43.6 (6.7) [11]
Lowest weight since eating disorder began (kg) – mean (SD)	36.9 (5.9) [9]	36.6 (6.1) [5]	36.7 (6.0) [14]
Highest weight ever (kg) – mean (SD)	57.6 (12.0) [16]	58.3 (11.4) [18]	57.9 (11.7) [34]

continued

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TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall (*continued*)

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Years with eating disorder			
Mean (SD)	7.8 (8.2) [4]	8.4 (8.3)	8.1 (8.3) [4]
Median (IQR)	5.0 (3.0–10.0) [4]	5.5 (3.0–10.0)	5.0 (3.0–10.0) [4]
Number of first-degree relatives with autism			
0	173 (93.0)	166 (90.2)	339 (91.6)
1	9 (4.8)	13 (7.1)	22 (6.0)
2	2 (1.1)	1 (0.5)	3 (0.8)
3	0 (0.0)	2 (1.1)	2 (0.5)
4	1 (0.5)	0 (0.0)	1 (0.3)
Missing	1 (0.5)	2 (1.1)	3 (0.8)
Number of first-degree relatives with an eating disorder			
0	159 (85.5)	164 (89.1)	323 (87.3)
1	22 (11.8)	16 (8.7)	38 (10.3)
2	3 (1.6)	1 (0.5)	4 (1.1)
3	1 (0.5)	0 (0.0)	1 (0.3)
Missing	1 (0.5)	3 (1.6)	4 (1.1)
Number of second-degree relatives with an eating disorder			
0	151 (81.2)	162 (88.0)	313 (84.6)
1	27 (14.5)	14 (7.6)	41 (11.1)
2	3 (1.6)	4 (2.2)	7 (1.9)
3	3 (1.6)	0 (0.0)	3 (0.8)
Missing	2 (1.1)	4 (2.2)	6 (1.6)
Number of first-degree relatives with a mental health illness			
0	92 (49.5)	90 (48.9)	182 (49.2)
1	48 (25.8)	52 (28.3)	100 (27.0)
2	30 (16.1)	24 (13.0)	54 (14.6)

TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall (*continued*)

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
3	10 (5.4)	9 (4.9)	19 (5.1)
4	1 (0.5)	5 (2.7)	6 (1.6)
5	1 (0.5)	0 (0.0)	1 (0.3)
6	1 (0.5)	0 (0.0)	1 (0.3)
7	1 (0.5)	0 (0.0)	1 (0.3)
Missing	2 (1.1)	4 (2.2)	6 (1.6)
Ever been diagnosed with depression?			
No	70 (37.6)	68 (37.0)	138 (37.3)
Yes	114 (61.3)	116 (63.0)	230 (62.2)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with anxiety?			
No	75 (40.3)	75 (40.8)	150 (40.5)
Yes	109 (58.6)	109 (59.2)	218 (58.9)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with OCD?			
No	157 (84.4)	151 (82.1)	308 (83.2)
Yes	27 (14.5)	33 (17.9)	60 (16.2)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with ADHD?			
No	182 (97.9)	177 (96.2)	359 (97.0)
Yes	2 (1.1)	7 (3.8)	9 (2.4)
Missing	2 (1.1)	0 (0.0)	2 (0.5)

continued

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TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall (*continued*)

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Ever been diagnosed with ASD?			
No	173 (93.0)	175 (95.1)	348 (94.1)
Yes	11 (5.9)	9 (4.9)	20 (5.4)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with panic disorder?			
No	175 (94.1)	170 (92.4)	345 (93.2)
Yes	9 (4.8)	14 (7.6)	23 (6.2)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with a phobia?			
No	168 (90.3)	175 (95.1)	343 (92.7)
Yes	16 (8.6)	9 (4.9)	25 (6.8)
Missing	2 (1.1)	0 (0.0)	2 (0.5)
Ever been diagnosed with any other psychological disorder?			
No	152 (81.7)	157 (85.3)	309 (83.5)
Yes	31 (16.7)	27 (14.7)	58 (15.7)
Missing	3 (1.6)	0 (0.0)	3 (0.8)
Ever treated under the MHA?			
1. Yes – currently	36 (19.4)	35 (19.0)	71 (19.2)
2. Yes – previously	32 (17.2)	30 (16.3)	62 (16.8)
3. No – never	118 (63.4)	118 (64.1)	236 (63.8)
Missing	0 (0.0)	1 (0.5)	1 (0.3)
If treated under the MHA, how many times?			
Mean (SD)	1.8 (1.0)	1.8 (1.1)	1.8 (1.0)
Median (IQR)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	2.0 (1.0–2.0)

TABLE 9 Summaries of patient baseline demographic and clinical variables by trial arm and overall (*continued*)

Patient variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Ever treated under a CTO?			
1. Yes – currently	6 (3.2)	6 (3.3)	12 (3.2)
2. Yes – previously	9 (4.8)	6 (3.3)	15 (4.1)
3. No – never	167 (89.8)	170 (92.4)	337 (91.1)
Missing	4 (2.2)	2 (1.1)	6 (1.6)

BTEC, Business and Technology Education Council; GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification.
a Baseline data were not available for one patient–carer dyad who were randomised in error study (see *Figure 5* – CONSORT).

Note
Square parentheses for continuous summaries represent number of missing entries (out of 370 patients). Where no square parentheses are present for continuous summaries, data are fully observed.

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TABLE 10 Summaries of carer baseline variables by trial arm and overall

Carer variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Age – mean (SD)	50.4 (12.7) [2]	49.9 (12.6) [2]	50.1 (12.6) [4]
Sex			
Male	55 (29.6)	56 (30.4)	111 (30.0)
Female	131 (70.4)	128 (69.6)	259 (70.0)
The patient is my			
Spouse	14 (7.5)	17 (9.2)	31 (8.4)
Partner	16 (8.6)	16 (8.7)	32 (8.6)
Child	140 (75.3)	141 (76.6)	281 (80.0)
Sibling	9 (4.8)	4 (2.2)	13 (3.5)
Parent	0 (0.0)	3 (1.6)	3 (0.8)
Other relative	2 (1.1)	1 (0.5)	3 (0.8)
Friend	4 (2.2)	2 (1.1)	6 (1.6)
Other non-relative	1 (0.5)	0 (0.0)	1 (0.3)
Current employment status			
Paid full-time employment	90 (48.4)	82 (44.6)	172 (46.5)
Paid part-time employment	43 (23.1)	47 (25.5)	90 (24.3)
Unpaid volunteer work	4 (2.2)	1 (0.5)	5 (1.4)
Sick leave	1 (0.5)	1 (0.5)	2 (0.5)
Unemployed	1 (0.5)	4 (2.2)	5 (1.4)
Student or pupil	2 (1.1)	4 (2.2)	6 (1.6)
Retired	20 (10.8)	20 (10.9)	40 (10.8)
House wife or house husband	11 (5.9)	15 (8.2)	26 (7.0)
Other	13 (7.0)	9 (4.9)	22 (6.0)
Missing	1 (0.5)	1 (0.5)	2 (0.5)
Highest completed education			
No qualifications	4 (2.2)	3 (1.6)	7 (1.9)
O Level/GCSE	32 (17.2)	37 (20.1)	69 (18.7)
A Level/NVQ	21 (11.3)	23 (12.5)	44 (11.9)
Diploma/BTEC	21 (11.3)	33 (17.9)	54 (14.6)
University degree	61 (32.8)	55 (29.9)	116 (31.4)
Postgraduate degree	39 (21.0)	30 (16.3)	69 (18.7)
Other	7 (3.8)	2 (1.1)	9 (2.4)
Missing	1 (0.5)	1 (0.5)	2 (0.5)
English as a first language			
No	3 (1.6)	6 (3.3)	9 (2.4)
Yes	182 (97.9)	177 (96.2)	359 (97.0)

TABLE 10 Summaries of carer baseline variables by trial arm and overall (*continued*)

Carer variable	TAU *N* = 186 *N* (%)	TAU + ECHOMANTRA *N* = 184[a] *N* (%)	Overall *N* = 370 *N* (%)
Missing	1 (0.5)	1 (0.5)	2 (0.5)
Ethnicity			
Asian	5 (2.7)	2 (1.1)	7 (1.9)
Black	2 (1.1)	0 (0.0)	2 (0.5)
White	174 (93.6)	178 (96.7)	352 (95.1)
Mixed	2 (1.1)	2 (1.1)	4 (1.1)
Other	1 (0.5)	1 (0.5)	2 (0.5)
Missing	2 (1.1)	1 (0.5)	3 (0.8)
Marital status			
Married	119 (64.0)	120 (65.2)	239 (64.6)
In a relationship and cohabiting	27 (14.5)	22 (12.0)	49 (13.2)
In a relationship and not cohabiting	9 (4.8)	7 (3.8)	16 (4.3)
Single	9 (4.8)	6 (3.3)	15 (4.1)
Divorced	17 (9.1)	16 (8.7)	33 (8.9)
Separated	2 (1.1)	6 (3.3)	8 (2.2)
Widowed	2 (1.1)	6 (3.3)	8 (2.2)
Missing	1 (0.5)	1 (0.5)	2 (0.5)
Number of daughters			
0	38 (20.4)	39 (21.2)	77 (20.8)
1	65 (35.0)	71 (38.6)	136 (36.8)
2	63 (33.9)	58 (31.5)	121 (32.7)
3	15 (8.1)	11 (6.0)	26 (7.0)
4	3 (1.6)	4 (2.2)	7 (1.9)
Missing	2 (1.1)	1 (0.5)	3 (0.8)
Number of sons			
0	69 (37.1)	85 (46.2)	154 (41.6)
1	81 (43.6)	69 (37.5)	150 (40.5)
2	24 (12.9)	21 (11.4)	45 (12.2)
3	9 (4.8)	5 (2.7)	14 (3.8)
4	0 (0.0)	2 (1.1)	2 (0.5)
Missing	3 (1.6)	2 (1.1)	5 (1.4)

GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification.
a Baseline data were not available for one patient–carer dyad randomised in error (see *Figure 5* – CONSORT).

Note
Square parentheses for continuous summaries represent number of missing entries (out of 370 carers). Where no square parentheses are present for continuous summaries, data are fully observed.

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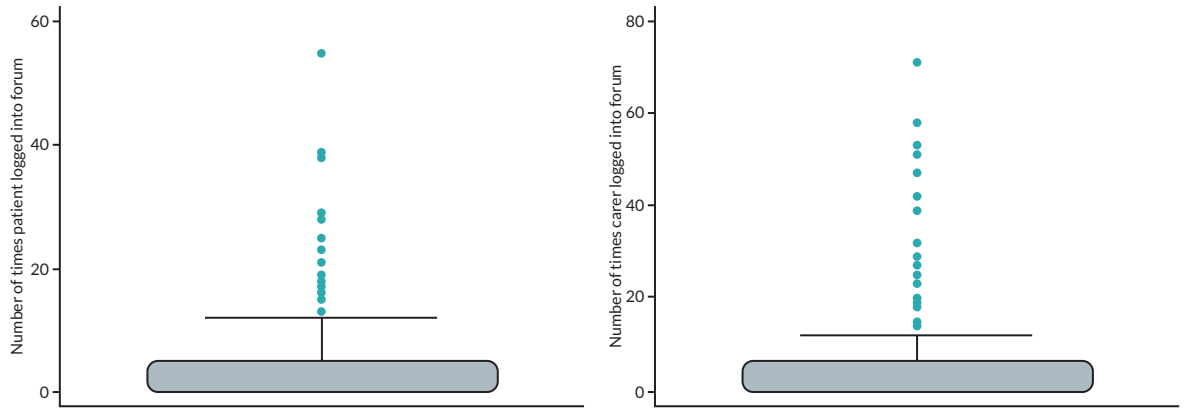

FIGURE 6 Box plot of the number of times each patient within the ECHOMANTRA arm logged into an online forum session (left) and the number of times each carer within the intervention arm logged into the online forum session (right). The median number of logins were zero for both patients and carers. Twenty-five per cent of the number of logins were more frequent than the upper ends of the boxes.

social adjustment (WSAS). The patients were moderately motivated to change but had low confidence in their ability to change. The primary outcome, patient distress (DASS) scores and secondary outcomes [eating psychopathology (EDEQ), BMI, work and social adjustment, motivation and ability to change, bed usage] were similar between groups at all time points.

As shown in *Table 11*, the median length of inpatient stay in the 3 months before recruitment into the study was 52 days (IQR 25–82, mean = 51.9). At 1-year follow-up, most patients were no longer in hospital, as indicated by a median of 0 inpatient days reported within 9–12 months post randomisation (IQR 0–1, mean = 14.7).

There were improvements in most outcome variables over time, but overall, there was a large amount of variation and a large proportion of missing data which may have led to biases and a lack of precision.

Carers

A total of 116 carers (43%) were missing distress (DASS-21) and carer skill (CASK) data at 12 months [TAU = 72 (39.1%), ECHOMANTRA = 95 (48%)]. The raw, unadjusted average values for each of the secondary carer outcome measures across all available time points are shown in *Table 12*. Carer distress (DASS) scores (see *Table 12* and *Figure 8*) and carer skills (CASK) scores (see *Table 12* and *Figure 9*) were not significantly different between groups at baseline and at all time points.

Primary outcome finding

The formal analysis of the primary outcome patient DASS-21 at 12 months was performed as detailed in *Chapter 2*, under the section heading Statistical Analysis. Since there was a considerable amount of missingness in the primary outcome, MI with 100 imputations was performed to avoid missing data biases. The imputation model employed here allowed for all variables of the analysis model (baseline DASS-21, trial arm, illness severity and 11 broad site categories; for details, see *Appendix 4*), extra measures of DASS-21 (at 9 or 18 months), a baseline variable empirically detected to predict missingness (variable 'Ever treated under the MHA followed by a CTO?'; for details, see *Appendix 5*, *Table 14*) to predict missing DASS-21 at 12 months.

We also checked whether there was an association between non-adherence with the ECHOMANTRA intervention and missing outcome values, as patients who discontinue the intervention might also drop out of the study. *Table 13* describes this association for the ECHOMANTRA arm (N = 184). The association between adherence to the intervention and missingness in the primary outcome was statistically significant [χ^2 (1) = 18.92, $p < 0.001$] with a larger proportion of patient outcomes observed (91.7%) for those who adhere to the intervention than those that do not (52.0%). We thus decided that it was important to allow adherence with ECHOMANTRA to predict missingness in the outcome and further included this variable in the imputation step of the MI procedure to reduce missing data biases.

TABLE 11 Summaries of patient outcome scales by assessment time point and trial arm

Patient outcome measure		Baseline			3 months			6 months			9 months			12 months			18 months		
		TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall
DASS-21	*N*	186	184	370	136	142	278	122	117	239	115	102	217	143	109	252	123	98	221
	Mean (SD)	71.7 (26.9)	68.7 (28.1)	70.2 (27.5)	60.3 (27.4)	60.8 (27.1)	60.5 (27.2)	58.1 (27.5)	59.8 (28.0)	58.9 (27.7)	60.4 (28.6)	60.8 (28.2)	60.6 (28.4)	61.7 (29.4)	58.3 (26.9)	60.2 (28.4)	56.9 (29.9)	56.3 (29.8)	56.6 (29.8)
EDE-Q	*N*	186	184	370	121	118	239	113	109	222	101	97	198	140	107	247	115	91	206
	Mean (SD)	3.9 (1.4)	3.8 (1.3)	3.9 (1.4)	3.5 (1.4)	3.4 (1.4)	3.5 (1.4)	3.4 (1.5)	3.4 (1.4)	3.4 (1.5)	3.3 (1.5)	3.3 (1.6)	3.3 (1.5)	3.5 (1.6)	3.4 (1.4)	3.5 (1.5)	3.3 (1.4)	3.3 (1.5)	3.3 (1.5)
	Median (IQR)	4.4 (3.2–5.0)	4.3 (3.1–4.9)	4.3 (3.1–4.9)	3.7 (2.5–4.7)	3.6 (2.5–4.6)	3.6 (2.5–4.7)	3.5 (2.4–5.0)	3.5 (2.3–4.5)	3.5 (2.3–4.8)	3.4 (2.2–4.7)	3.4 (1.9–4.9)	3.4 (2.0–4.7)	3.7 (2.2–4.9)	3.4 (2.3–4.4)	3.6 (2.2–4.7)	3.5 (2.1–4.5)	3.4 (2.3–4.6)	3.5 (2.2–4.5)
Patient-reported BMI	*N*	179	179	358	131	132	263	109	108	217	102	94	196	132	98	230	112	87	199
	Mean (SD)	15.9 (2.1)	15.9 (2.0)	15.9 (2.0)	17.4 (2.2)	16.9 (1.9)	17.1 (2.1)	17.3 (2.5)	17.0 (2.4)	17.2 (2.4)	17.5 (2.6)	16.9 (2.2)	17.2 (2.5)	17.4 (2.8)	16.9 (2.3)	17.2 (2.6)	17.6 (2.7)	17.3 (2.7)	17.5 (2.7)
WSAS	*N*	185	184	369	–	–	–	111	104	215	–	–	–	134	108	242	115	91	206
	Mean (SD)	25.0 (9.3)	23.3 (9.2)	24.1 (9.3)	–	–	–	20.3 (9.9)	19.1 (9.9)	19.7 (9.9)	–	–	–	18.0 (12.0)	18.4 (10.8)	18.2 (11.5)	16.0 (10.8)	17.0 (11.8)	16.5 (11.3)
	Median (IQR)	26.0 (18.0–32.0)	24.0 (17.0–30.0)	25.0 (17.0–31.0)	–	–	–	20.0 (12.0–29.0)	18.0 (10.5–27.5)	19.0 (11.0–28.0)	–	–	–	17.0 (8.0–28.0)	17.0 (9.0–27.0)	17.0 (8.0–27.0)	14.0 (7.0–24.0)	15.0 (8.0–25.0)	14.0 (7.0–24.0)
Motivation to change	*N*	185	184	369	121	118	239	113	109	222	–	–	–	134	107	241	114	91	205
	Mean (SD)	7.0 (2.8)	7.1 (2.7)	7.1 (2.8)	7.2 (2.8)	7.3 (2.4)	7.3 (2.6)	7.1 (2.7)	7.2 (2.5)	7.1 (2.6)	–	–	–	6.8 (2.9)	7.0 (2.6)	6.9 (2.8)	6.8 (2.7)	6.6 (3.0)	6.7 (2.8)
	Median (IQR)	8.0 (5.0–10.0)	8.0 (5.0–10.0)	8.0 (5.0–10.0)	8.0 (6.0–10.0)	8.0 (6.0–9.0)	8.0 (6.0–10.0)	8.0 (6.0–10.0)	8.0 (6.0–9.0)	8.0 (6.0–9.0)	–	–	–	8.0 (4.0–10.0)	7.0 (5.0–10.0)	8.0 (5.0–10.0)	7.5 (5.0–9.0)	7.0 (4.0–10.0)	7.0 (5.0–9.0)

continued

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TABLE 11 Summaries of patient outcome scales by assessment time point and trial arm (*continued*)

Patient outcome measure		Baseline			3 months			6 months			9 months			12 months			18 months		
		TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall
Ability to change	*N*	185	184	369	121	118	239	113	109	222	–	–	–	134	108	242	114	91	205
	Mean (SD)	3.9 (2.6)	4.2 (2.7)	4.0 (2.7)	3.9 (2.6)	4.2 (2.6)	4.1 (2.6)	4.1 (2.6)	4.0 (2.7)	4.1 (2.6)	–	–	–	3.8 (2.8)	3.9 (2.6)	3.8 (2.7)	4.1 (2.7)	3.9 (2.7)	4.0 (2.7)
	Median (IQR)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	4.0 (2.0–6.0)	4.0 (2.0–6.0)	4.0 (2.0–6.0)	3.0 (2.0–6.0)	4.0 (2.0–6.0)	–	–	–	3.0 (2.0–6.0)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	4.0 (2.0–6.0)	3.0 (2.0–6.0)	3.0 (2.0–6.0)
SDQ	*N*	185	182	367	–	––	–	–	–	–	–	–	–	107	83	190	–	–	–
Total scale	Mean (SD)	19.6 (6.1)	18.8 (5.5)	19.2 (5.8)	–	–	–	–	–	–	–	–	–	15.9 (6.9)	17.2 (7.1)	16.5 (7.0)	–	–	–
Peer problems subscale	Mean (SD)	3.4 (2.0)	3.3 (1.9)	3.3 (2.0)	–	–	–	–	–	–	–	–	–	3.0 (2.0)	3.1 (2.0)	3.0 (2.0)	–	–	–
Prosocial subscale	Mean (SD)	6.5 (2.2)	6.6 (2.2)	6.6 (2.2)	–	–	–	–	–	–	–	–	–	6.8 (2.3)	6.7 (2.0)	6.8 (2.2)	–	–	–
CSRI	*N*	185	184	369	–	–	–	–	–	–	–	–	–	134	108	242	–	–	–
Inpatient hospital days during prior 3 months	Mean (SD)	51.0 (35.6)	52.8 (34.9)	51.9 (35.3)	–	–	–	–	–	–	–	–	–	14.4 (30.5)	14.9 (31.3)	14.7 (30.8)	–	–	–
	Median (IQR)	46.0 (23.0 – 81.0)	56.0 (28.0 – 82.0)	52.0 (25.0 – 82.0)	–	–	–	–	–	–	–	–	–	0.0 (0.0–1.0)	0.0 (0.0–3.0)	0.0 (0.0–1.0)	–	–	–

Note
For continuous measures with skewed distributions, both the mean (SD) and median (IQR) are provided. Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

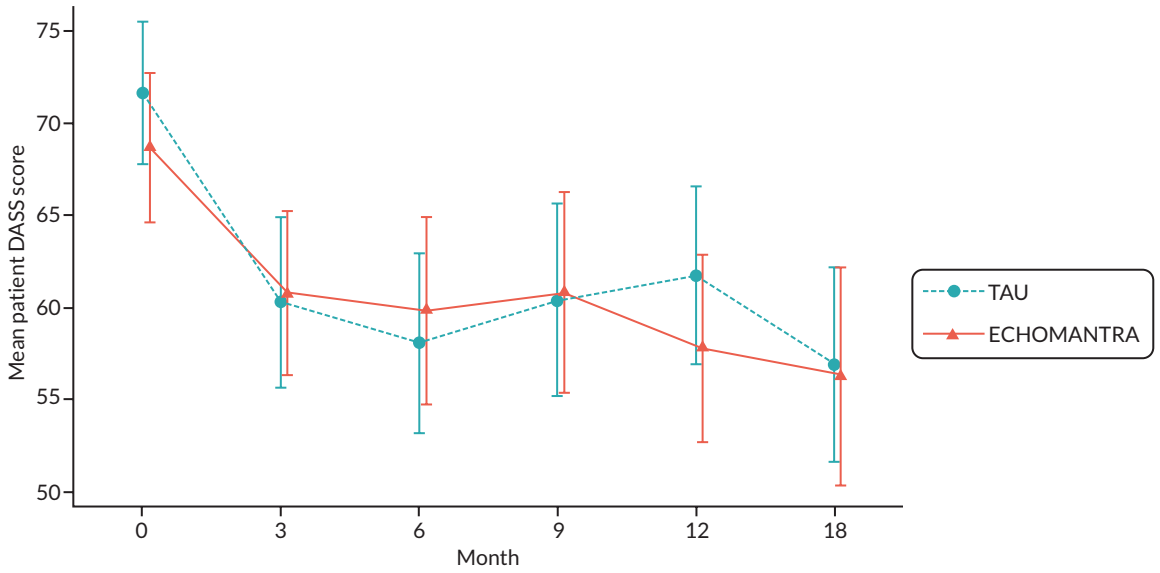

FIGURE 7 Profile plots displaying changes in raw mean scores (with 95% CIs) over time by trial arm for patient DASS scores.

Table 14 shows the result of the primary outcome analysis. No evidence of a statistically significant effect of ECHOMANTRA on DASS-21 at 12 months was found (p = 0.87), with 95% CIs spanning the null (95% CI −5.36 to 6.33).

Secondary outcomes findings

Tables 15 and *16* show formal results for the 18 patient and carer secondary outcome measures, respectively. As with the analysis of the primary outcome, MICE was used with 100 imputations to correct for missing data biases. WSAS at 18 months post randomisation was the only patient secondary outcome found to be associated with the ECHOMANTRA intervention at $p < 0.05$, with an estimated treatment effect of 3.42 (95% CI 0.53 to 6.31). All standardised effect size estimates for secondary patient outcomes, except for WSAS, were small. Carer outcomes were not found to differ between trial arms, and respective standardised effect size estimates were also of small size.

Exploration of work and social adjustment scale scores

The effect of ECHOMANTRA at 18 months suggesting slightly worse scores in the TAU + ECHOMANTRA arm compared to TAU alone was unexpected. Here we try to understand what contributed to this effect estimate. We walk the reader through the various adjustments made by the final analysis. First, any analysis will need to adjust for baseline differences. *Figure 10* shows that mean WSAS scores at baseline were somewhat lower in the ECHOMANTRA arm, while at 18 months they were higher than in the TAU group. Thus, any adjustment for baseline differences will increase the estimated WSAS difference at 18 months. This is confirmed by the complete-case analysis (CCA), which adjusts for baseline differences but not for any missing data biases (see *Appendix 6*, *Tables 19* and *20*). While the raw mean difference for WSAS at 18 month is + 1 (ECHOMANTRA – TAU, *Table 11*), after adjustment for a baseline difference of −1.7, the CC analysis estimates an effect of + 2.19 (see *Appendix 6*, *Table 19*). Note that the CC analysis also adjusts for further variables illness severity and site. Second, the MI approach aims to adjust for possible missing data biases (see *Appendix 7*, *Tables 21* and *22*). *Appendix 7*, *Table 21*, which provides the results after further adjusting for missing data biases due to variables MHA/CTO or broad site categories, estimates a larger effect of + 2.8. Finally, the MI results presented in *Table 15* also adjust for missing data biases due to non-adherence with ECHOMANTRA predicting missing outcome values. We see that this leads to a further increase in effect size estimate to + 3.42 and now also testing significant at a 5% level. The latest adjustment can be understood by considering *Figure 10*, which shows that the compliers in the ECHOMANTRA arm continue to improve to 18 months (red line), while the non-compliers in the ECHOMANTRA arm tend to stabilise after 6 months (green line) and interestingly have worse (larger) values than the

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TABLE 12 Carer outcome scales split by time point and arm

Carer outcome measure		Baseline			3 months			6 months			9 months			12 months			18 months		
		TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall	TAU	ECHO	Overall
DASS-21	*N*	186	184	370	136	130	266	112	111	223	97	85	182	114	95	209	102	79	181
	Mean (SD)	31.7 (24.9)	32.1 (23.8)	31.9 (24.3)	30.9 (22.6)	29.9 (20.6)	30.4 (21.6)	30.4 (24.5)	31.4 (23.8)	30.9 (24.1)	26.1 (20.2)	27.6 (20.1)	26.8 (20.1)	29.6 (22.7)	27.6 (18.7)	28.7 (20.9)	29.7 (22.5)	26.6 (18.9)	28.4 (21.0)
	Median (IQR)	26.0 (12.0–42.0)	26.0 (14.0–44.0)	26.0 (14.0–44.0)	29.0 (14.0–42.0)	26.0 (14.0–42.0)	27.0 (14.0–42.0)	24.0 (13.0–41.0)	26.0 (12.0–40.0)	24.0 (12.0–40.0)	20.0 (12.0–38.0)	24.0 (14.0–34.0)	22.0 (12.0–38.0)	25.0 (12.0–40.0)	24.0 (16.0–36.0)	24.0 (14.0–38.0)	27.0 (14.0–38.0)	22.0 (14.0–34.0)	26.0 (14.0–36.0)
CASK	*N*	185	182	367	–	–	–	98	97	195	–	–	–	108	86	194	96	74	170
	Mean (SD)	156.4 (41.3)	156.5 (40.2)	156.5 (40.7)	–	–	–	155.0 (49.8)	154.9 (44.6)	155.0 (47.2)	–	–	–	164.8 (50.3)	152.6 (52.3)	159.4 (51.5)	161.0 (54.0)	170.2 (50.7)	165.0 (52.6)

Note
Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

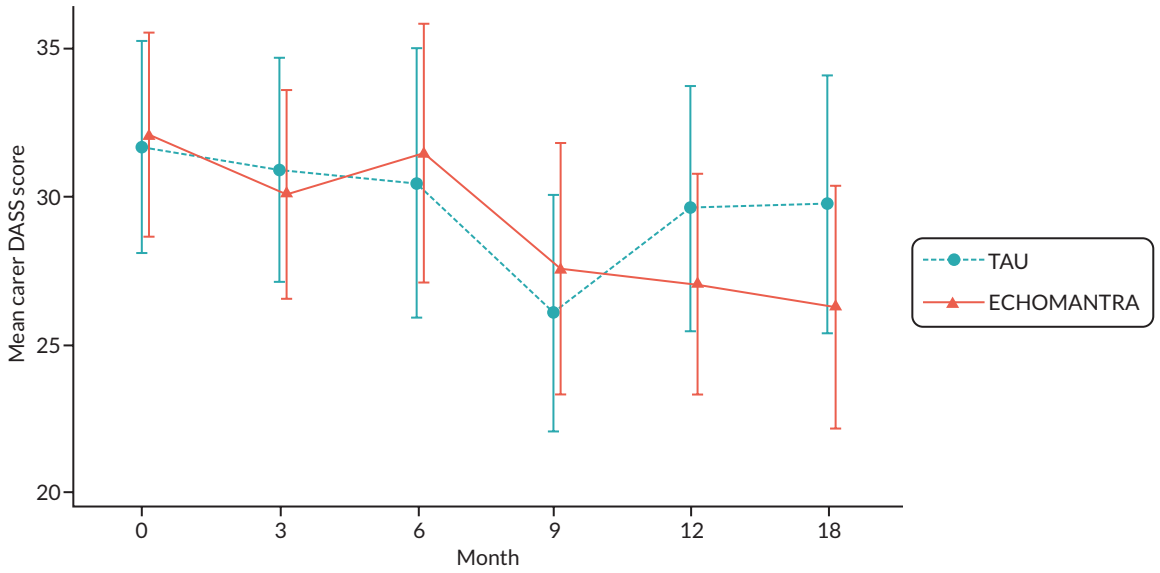

FIGURE 8 Profile plots displaying changes in raw mean scores (with 95% CIs) over time by trial arm for carer DASS scores.

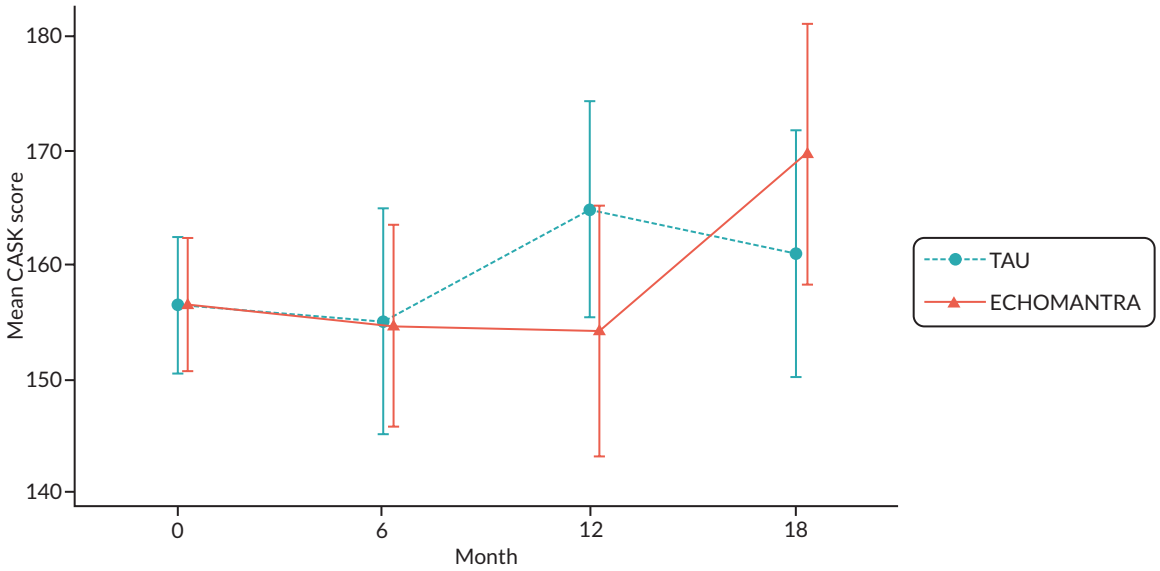

FIGURE 9 Profile plots displaying changes in raw mean scores (with 95% CIs) over time by trial arm for carer CASK scores.

TABLE 13 Adherence with ECHOMANTRA split by participant missingness of DASS-21 at 12-month follow-up

Adhered with ECHOMANTRA	Participants with DASS-21 observed at 12 months *N* = 110 – *N* (%)	Participants with DASS-21 missing at 12 months *N* = 74 – *N* (%)
No	77 (52)	71 (48)
Yes	33 (92)	3 (8)

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TABLE 14 Primary outcome analysis result adjusting for missing data biases using MI

Primary outcome	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	370	0.48	(−5.36 to 6.33)	0.02	(−0.20 to 0.23)	0.87

TABLE 15 Secondary outcome analyses results for patients adjusting for missing data biases using MI

Patient secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 18 months	370	1.35	(−5.33 to 8.02)	0.05	(−0.19 to 0.29)	0.69
EDE-Q – 12 months	370	−0.01	(−0.28 to 0.27)	0.00	(−0.21 to 0.20)	0.97
EDE-Q – 18 months	370	0.08	(−0.24 to 0.40)	0.06	(−0.17 to 0.29)	0.62
Patient report BMI – 12 months	370	−0.52	(−1.13 to 0.09)	−0.25	(−0.55 to 0.04)	0.09
Patient report BMI – 18 months	370	−0.34	(−1.02 to 0.34)	−0.17	(−0.50 to 0.17)	0.33
WSAS – 12 months	370	1.87	(−0.81 to 4.55)	0.20	(−0.09 to 0.49)	0.17
WSAS – 18 months	370	3.42	(0.53 to 6.31)	0.37	(0.06 to 0.68)	0.021*
Motivation to change – 12 months	370	0.17	(−0.51 to 0.85)	0.06	(−0.18 to 0.31)	0.62
Motivation to change – 18 months	370	−0.09	(−0.82 to 0.64)	−0.03	(−0.30 to 0.23)	0.81
Ability to change – 12 months	370	−0.10	(−0.72 to 0.51)	−0.04	(−0.27 to 0.19)	0.74
Ability to change – 18 months	370	−0.20	(−0.87 to 0.47)	−0.07	(−0.33 to 0.18)	0.56
SDQ – 12 months	370	1.24	(−0.38 to 2.86)	0.21	(−0.06 to 0.49)	0.13
	N	IRR	95% CI	–	–	*p*-value
EQ-5D-3L – 12 months	370	−0.02	(−0.09 to 0.05)	0.00	(−0.20 to 0.20)	0.62
CSRI – inpatient hospital days in 3 months prior to 12 months follow-up	370	0.86	(0.31 to 2.41)	–	–	0.77

IRR, incidence rate ratio.
*$p < 0.05$.

Note
Shaded cells indicate measures whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

TABLE 16 Secondary outcome analyses results for carers adjusting for missing data biases using MI

Carer secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	370	−1.4	(−6.19 to 3.38)	−0.06	(−0.25 to 0.14)	0.57
DASS-21 – 18 months	370	−2.12	(−7.42 to 3.18)	−0.09	(−0.31 to 0.13)	0.43
CASK – 12 months	370	−11.96	(−24.47 to 0.55)	−0.29	(−0.60 to 0.01)	0.06
CASK – 18 months	370	7.08	(−7.02 to 21.17)	0.17	(−0.17 to 0.52)	0.32

Note
Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

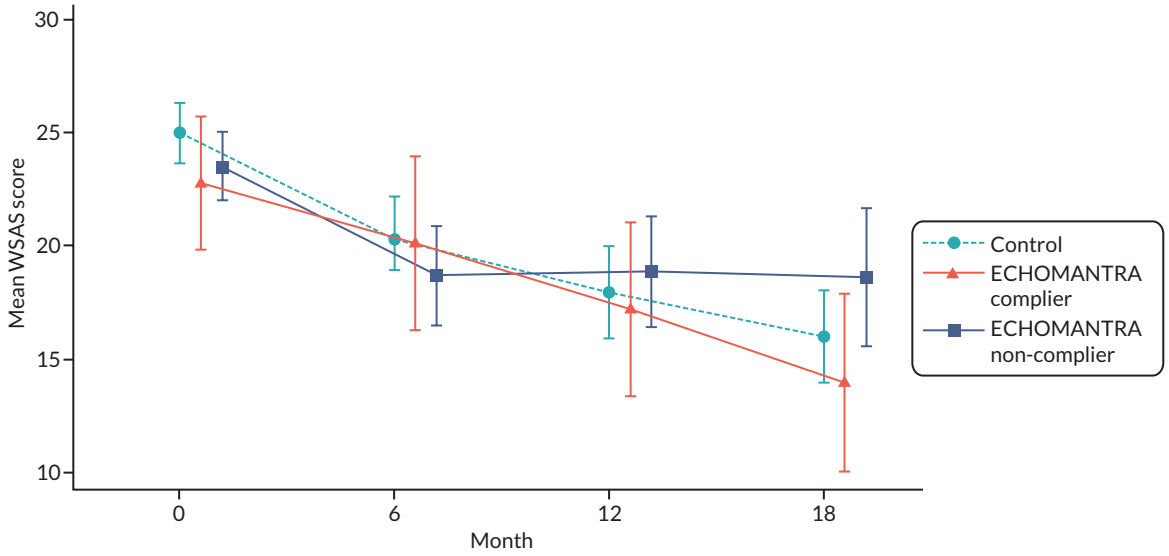

FIGURE 10 Profile plot displaying changes in raw WSAS mean scores (with 95% CIs) over time, split by complier group – ECHOMANTRA compliers (red triangle), ECHOMANTRA non-compliers (green square) and controls (blue circle).

TAU arms. Since non-adherence predicts missingness, adherers are over-represented in the observed data. The imputed WSAS values for the missing cases will tend to be larger values for non-adherers, leading to an increase in the imputed mean in the ECHOMANTRA group.

Sensitivity analyses

We carried out three sensitivity analyses of the primary outcome to check the sensitivity/robustness of findings to changing assumptions.

Efficacy of the intervention

To assess the effect of treatment receipt, as opposed to treatment assignment, on the primary outcome of DASS-12 scores at 12 months post randomisation, the CACE was estimated. For this purpose, ECHOMANTRA receipt was measured by a binary variable (both the patient and carer attending a minimum of four online group sessions) and random treatment allocation utilised as an instrumental variable to enable estimation of the CACE via two-stage least squares regression. Results from this CACE analysis are presented in *Table 17*. As with the primary outcome analysis, no evidence of a statistically significant effect of treatment receipt was observed on DASS-12 scores at 12 months, although the effect estimate was increased. However, due to the low level of adherence (only 20%), very wide CIs indicate limited precision to detect an effect (95% CI −26.92 to 33.13).

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TABLE 17 Complier-average causal effect results

Outcome	*N*	Estimate	*p*-value	95% CI
DASS-21 – 12 months	370	3.11	0.84	(−26.92 to 33.13)

TABLE 18 Results for primary outcome after removing ineligible patients

Outcome	*N*	Estimate	*p*-value	95% CI
DASS-21 – 12 months	367	0.28	0.92	(−5.58 to 6.15)

TABLE 19 Results for primary outcome after excluding data collected after 11 March 2020

Outcome	*N*	Estimate	*p*-value	95% CI
DASS-21 – 12 months	337	1.71	0.70	(−7.15 to 10.57)

TABLE 20 Patient AEs by trial arm and overall

	TAU	TAU + ECHOMANTRA	Overall
Is the event serious? ***N (%)***			
No	3 (3.2)	2 (2.2)	5 (2.7)
Yes	91 (96.8)	87 (97.8)	178 (97.3)
Resulted in death? *N* (%)	3 (3.2)	2 (2.3)	5 (2.7)
AE type: ***Events (people)***			
Cardiovascular	0 (0)	2 (2)	2 (2)
Respiratory	1 (1)	1 (1)	2 (2)
Gastrointestinal	2 (2)	0 (0)	2 (2)
Genitourinary/renal	0 (0)	1 (1)	1 (1)
Psychological	89 (67)	84 (61)	173 (128)
Immunological	2 (2)	0 (0)	2 (2)
Intensity of AE ***N (%)***			
Mild	3 (3.2)	1 (1.1)	4 (2.2)
Moderate	58 (61.7)	39 (44.3)	97 (53.3)
Severe	33 (35.1)	48 (54.5)	81 (44.5)
Relationship of AE to study participation ***N (%)***			
Definitely related	0 (0.0)	1 (1.1)	1 (0.5)
Not related	94 (100.0)	88 (98.9)	182 (99.5)

TABLE 21 Psychological AEs – subcategories by trial arm and overall

	TAU Events (people)	TAU + ECHOMANTRA Events (people)	Overall Events (people)
Psychological AEs – subcategories			
Weight loss > 1 kg	80 (64)	64 (51)	144 (115)
Self-harm	0 (0)	4 (4)	4 (4)
Suicidality	2 (1)	0 (0)	2 (1)
Re/admission due to psych instability	4 (3)	8 (8)	12 (11)
Psychological distress	0 (0)	6 (5)	6 (5)
Death	3 (3)	2 (2)	5 (5)

Sensitivity to violating eligibility criteria

To ensure that results observed for our primary outcome measure were not impacted by the presence of participants recruited into the study with atypical AN, these participants were removed, and the primary analysis model was rerun as a sensitivity analysis. *Table 18* demonstrates that results for the primary analysis did not change substantially upon removal of these three patients, with the association to the ECHOMANTRA intervention remaining non-statistically significant (95% CI −5.58 to 6.15).

Impact of COVID-19

This trial started prior to the onset of the COVID-19 pandemic and ended after the acute pandemic period. As the intervention provision should be unaffected by the COVID crisis and the population covered by the desired treatment effect includes dyads recruited during the COVID period, we did not make any changes to the intended analysis.

However, as pre-specified within the study's SAP (internal document), *Appendix 4*, *Tables 25–28* display baseline descriptive statistics of the groups split by those recruited before and after 11 March 2020 (as defined by a randomisation date after 11 March 2020, *N* = 33), overall and by trial arm, for both patients and carers, respectively. This shows no significant differences in baseline descriptive statistics between participants recruited before or after the onset of the COVID-19 pandemic. *Appendix 5*, *Tables 29–30* further report 12-month outcome descriptive statistics split by visit date before and after 11 March 2020 for patient and carer outcomes. Again, this shows no significant differences in outcomes between participants recruited before or after the onset of the COVID-19 pandemic.

Finally, *Table 19* provides a sensitivity analysis of the primary outcome analysis by excluding all data collected after 11 March 2020. As with the primary analysis, results remained non-statistically significant when considering only the pre-COVID population (95% CI −7.15 to 10.57).

Adverse events

Patient adverse events

Table 20 provides an overview of the AEs which occurred in patients across the duration of the trial (from baseline until study completion). The proportion of AE types were comparable across arms. There were five patient deaths (two from suicide and three from physical complications) over the course of the trial. All AEs logged as 'Respiratory' (*N* = 2) were due to COVID-19 symptoms. Three non-serious events were classified as related to trial participation. One carer reported that her daughter (the patient) found the first joint patient–carer session (delivered via videoconference) stressful and was feeling overwhelmed about the prospect of attending both the study Zoom (Zoom Video Communications, San Jose, CA, USA) sessions alongside her usual therapy. Two carers reported that completing the questionnaires elicited distress in themselves.

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Table 21 shows an overview of the psychological AEs which occurred in patients across the duration of the trial (from baseline until study completion). Weight loss and deaths are categorised as psychological events, as these are all side effects of AN. The proportion of AE types were comparable across arms.

Carer adverse events

Table 22 provides an overview of the AEs which occurred in carers across the duration of the trial (from baseline until study completion). Five AEs in carers were recorded in total across the study duration, with comparable proportions across arms (TAU = 2 events, ECHOMANTRA = 3 events). Of the events logged for carers, none were classified as serious, and were either respiratory (*N* = 2), both logged as COVID-19 symptoms or psychological in nature (*N* = 3). Of those classified as psychological, all were related to carer psychological distress.

Patient concomitant medications

Concomitant medications taken by patients across the duration of the study (any time between baseline and study completion) are shown in *Table 23*. Antidepressant and major tranquilisers and antianxiety medications were most commonly consumed, with similar proportions across each arm.

TABLE 22 Carer AEs, by arm and overall

	TAU	ECHOMANTRA	Overall
Is the event serious? N (%)			
No	2 (100.0)	3 (100.0)	5 (100.0)
AE type – events (people)			
Respiratory	0 (0)	2 (2)	2 (2)
Psychological	2 (2)	1 (1)	3 (3)
Intensity N (%)			
Mild	2 (100.0)	2 (66.7)	4 (80.0)
Moderate	0 (0.0)	1 (33.3)	1 (20.0)
Relationship to study participation N (%)			
Definitely related	2 (100.0)	0 (0.0)	2 (40.0)
Not related	0 (0.0)	3 (100.0)	3 (60.0)

TABLE 23 Patient concomitant medications

Medication type	TAU events (people)	ECHOMANTRA events (people)	Overall events (people)
Major tranquiliser	85 (66)	66 (54)	151 (120)
Antidepressant	202 (134)	182 (125)	384 (259)
Antianxiety	73 (47)	75 (49)	148 (96)
Mood stabiliser	10 (9)	1 (1)	11 (10)
Other: sleep aid	5 (5)	6 (6)	11 (11)
Other: stimulant	0 (0)	1 (1)	1 (1)

Summary of results

- The trial sample was representative of a population of adult patients with AN and their carers admitted for inpatient/day patient treatment.
- There was no evidence to suggest that the offer of the ECHOMANTRA add-on treatment affected patient or carer outcomes.
- Over time, the data suggest that most outcome variables improved, although patients remained symptomatic. However, motivation for change reduced, and the self-rated ability to change remained low.
- Based on the limited participant-level data regarding the use of the ECHOMANTRA materials, it seems that uptake of the ECHOMANTRA offer was suboptimal, with most dyads not actually adhering to the pre-defined dose of the intervention when allocated to the ECHOMANTRA arm.
- Most of the adverse effects recorded were related to signs of relapse of the eating disorder (i.e. weight loss).
- Five patients died during the study (no difference between the groups).

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Chapter 4 Health economic evaluation

Introduction

An economic evaluation was conducted alongside the TRIANGLE RCT to assess the cost-effectiveness of investing in ECHOMANTRA + TAU compared to TAU alone. The principal objectives of the economic evaluation were:

1. To identify the additional resources and costs associated with the delivery of ECHOMANTRA.
2. To measure the use of selected health services, as well as impacts on productivity and out-of-pocket expenditure by patients in the study.
3. To estimate the mean healthcare costs per person living with AN in the intervention and TAU groups.
4. To estimate the health benefits of the trial interventions using QALYs calculated using the EQ-5D-3L.
5. To estimate incremental cost-effectiveness ratios (ICERs), for example, the incremental cost per QALY gained between the ECHOMATRA + TAU and TAU-only groups.
6. To undertake sensitivity analysis to assess the impacts of uncertainty around the calculated ICERs using the bootstrapping method and to generate cost-effectiveness planes and acceptability curves.

Methods

Overview

The report of this health economic evaluation followed the Consolidated Health Economics Evaluation Reporting Standards guidance.[99] The economic evaluation was conducted using individual participant cost and effect data collected alongside the TRIANGLE trial. The time horizon of the analysis was 12 months with two assessment points: baseline and 12-month follow-up.

Study perspective

The economic analysis was performed from both a healthcare system and a broader societal perspective, including productivity impacts on patients from lost employment and volunteering. The analysis was conducted on an intention-to-treat basis, and all costs are reported in 2021–2 Great British pounds, and discounting was not applied given the short duration of follow-up.

Implementation costs, health service use, productivity impacts and out-of-pocket expenses

A micro-costing approach was adopted to estimate the additional resource use and costs associated with ECHOMANTRA. Resource use information was obtained from project records; these included costs associated with the delivery of group online therapy sessions, training and supervision of session facilitators and moderators, as well as costs associated with web-design and platform hosting and workbooks given to participants.

Data on health service utilisation for the previous 3 months were collected at baseline and 12 months using a modified online version of the CSRI, an instrument widely used in economic evaluation to collect self-reported information both on health service and wider resource impacts such as time out of employment.[95] *Table 24* shows the resource impacts that were measured by the CSRI. In addition to inpatient, outpatient and community health service utilisation, the CSRI also asked for time out of employment and volunteering. Information on a range of additional out-of-pocket expenses incurred by patients due to AN were also included, such as information on the need for special food, clothes and cleaning products, as well as additional child care, travel and other expenses. The protocol for the trial only specified the collection of health economic data at just two time points, baseline and 12-month follow-up, making it challenging to estimate 12-month annual costs in the two groups. This is a limitation of the analysis. To approximate annual health and societal cost perspectives, we adopted an area under the curve approach, using the trapezium rule, making use of baseline and 12-month follow-up data.

Unit costs for resource use

Appropriate unit costs were attached to health services shown in *Table 24*, including specialist inpatient care, as well as outpatient visits and community service contacts. *Table 25* shows sources of unit costs; these were drawn from the 2022 edition of the *Unit Costs of Health and Social Care*,[100] as well as the *National Schedule of NHS Costs 2020–2021*,[101] with costs for the latter updated to 2022 prices using the NHS Cost Inflation Index. All patient productivity losses were valued using annual full-time gross pay by occupation as listed by the Office for National Statistics (ONS), using data from the Annual Survey for Hours and Earnings.[102] Where individuals who did not list an occupation or were listed as a student reported days out of work, these were valued using age-specific minimum wage rates for 2022.[103] Time out of volunteering was valued at the same wage rate used for time out of employment for each study participant, as this best reflects the opportunity costs of time spent volunteering, rather than valuing all volunteering time at the minimum wage rate.

TABLE 24 Health service use, productivity losses and out-of-pocket expenses included in CSRI

Inpatient health service use
Eating disorder unit inpatient stays (days)
Other psychiatric inpatient stays (days)
Other inpatient stays (days)
Outpatient and day services
Eating disorder unit day patient (days)
Other outpatient services (visits)
Accident and emergency dept/minor injury unit (visits)
Primary and community services
GP consultations
GP practice nurse consultations
Dietician (contacts)
Dentist (contacts)
Other unspecified services (contacts)
Productivity losses
Time out of full-time and part-time employment (hours)
Time out of volunteering (hours)
Out-of-pocket expenses
Direct expenses, for example, clothes, special or extra food
Over-the-counter medication expenses
Employing extra help, for example, child care
Travel expenses to treatment sessions
Other personal expenses such as cleaning products

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TABLE 25 Unit costs used in the economic evaluation (2022 £s)

Type of cost	Unit cost	Unit	Source
GP	£42	Per consultation	Unit Costs of Health and Social Care 2022
Practice nurse	£8.67	Per consultation	Unit Costs of Health and Social Care 2022 (assume a 10-minute consultation)
Dentist	£53.34	Per consultation	Unit Costs of Health and Social Care 2022 (assume a 10-minute consultation) for provider-performer and assumes average consultation time 20 minutes
Dietician	£100	Per consultation	Unit Costs of Health and Social Care 2022
Eating disorder unit inpatient	£645	Per night	NHS England National Schedule of NHS Costs 2020–21
Eating disorder unit day patient	£261	Per day	NHS England National Schedule of NHS Costs 2020–21 for outpatient attendances
Inpatient psychiatric stays	£469	Per day	NHS England National Schedule of NHS Costs 2020–21 for other specialist mental health services inpatient stay
Hospital general inpatient stays (long stay)	£4974	Finished consultant episode	NHS England National Schedule of NHS Costs 2020–21 Non-Elective (stays of more than 5 days)
Hospital general inpatient stays (short stay)	£985	Finished consultant episode	NHS England National Schedule of NHS Costs 2020–21 Non-Elective (assumes no more than 5-day stay)
Hospital general outpatient contact	£235	Per consultation	Unit Costs of Health and Social Care 2022 (average of NHS national costs for all outpatient contacts)
Hospital A&E attendance	£304	Per visit	NHS England National Schedule of NHS Costs 2020–21 (average cost for all A&E activity)
Actors, entertainers and presenters	£15.54	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Bakers and flour confectioners	£13.76	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Nursing auxiliaries and assistants	£14.74	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Cleaners and domestics	£12.36	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Youth and community workers	£17.91	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Teaching assistants	£11.03	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Early education and childcare assistants	£12.20	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Primary education teaching professionals	£24.50	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Medical radiographers	£27.47	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Receptionists	£12.86	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Community nurses	£22.85	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Marketing managers	£29.97	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Managers and directors in retail and wholesale	£20.00	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Solicitors and lawyers	£31.14	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Sports coaches, instructors and officials	£16.62	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Researchers, unspecified discipline	£24.44	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Higher education Teaching professionals	£30.32	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Generalist medical practitioners	£27.89	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Specialist medical professionals	£43.98	Per hour	ONS April 2022 Employee Earnings in the UK 2022

TABLE 25 Unit costs used in the economic evaluation (2022 £s) (*continued*)

Type of cost	Unit cost	Unit	Source
Physiotherapists	£25.24	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Management consultants and business analysts	£28.13	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Health services and public health managers	£32.56	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Hairdressers and barbers	£11.56	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Beauticians and related occupations	£11.95	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Chartered and certified accountants	£27.99	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Legal secretaries	£14.52	Per hour	ONS April 2022 Employee Earnings in the UK 2022
IT quality and testing professionals	£27.56	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Cooks	£12.46	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Chartered architectural technologists, planning officers and consultants	£21.76	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Authors, writers and translators	£19.28	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Project support officers	£19.21	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Midwifery nurses	£26.00	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Public relations and communications directors	£42.63	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Wholesaling, retailing, hotel and restaurant staff	£11.63	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Unspecified public sector workers (excluding financial services)	£16.74	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Elementary administrative occupations	£12.81	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Business and financial project management professionals	£32.24	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Marketing associate professionals	£18.69	Per hour	ONS April 2022 Employee Earnings in the UK 2022
CAD, drawing and architectural technicians	£20.03	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Managers and proprietors in agriculture and horticulture	£22.03	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Human resources administrative occupations	£14.64	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Managers and proprietors in unspecified services	£20.55	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Psychotherapists and CBT therapists	£22.86	Per hour	ONS April 2022 Employee Earnings in the UK 2022
Minimum wage rate aged 16–17 (April 2022)	£4.81	Per hour	GOV.UK Minimum Wage Rates for 2022
Minimum wage rate aged 18–20 (April 2022)	£6.83	Per hour	GOV.UK Minimum Wage Rates for 2022
Minimum wage rate aged 21–22 (April 2022)	£9.18	Per hour	GOV.UK Minimum Wage Rates for 2022
Minimum wage rate aged 23 + (April 2022)	£9.50	Per hour	GOV.UK Minimum Wage Rates for 2022

A&E, accident and emergency.

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Health outcome measures

In addition to the primary and secondary outcome measures reported in *Chapter 3*, the primary health outcome measure used in the economic evaluation was the QALY. The QALY is the reference case outcome recommended by NICE for use in economic evaluations[104] and allows for the comparison of the economic case for intervention across all health-related interventions, regardless of the specific health condition being assessed. In this analysis, QALYs were calculated using the area under the curve approach, following the trapezium rule, making use of utility scores measured by EQ-5D-3L questionnaire collected online at baseline and at 12-month follow-up.

The EQ-5D-3L is a generic measure of quality of life that contains five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression, each of which has three levels indicating no problem, some or a moderate problem and a major problem.[94] There are 243 possible health states (plus unconsciousness and death). EQ-5D-3L questionnaire responses from participations were transformed into a preference-based index utility score using published UK population tariffs calculated using the time trade-off method.[94,105] Perfect health has a utility value of 1, and death a value of 0; some health states can have negative values, reflecting perceptions of the population that they are worse than death.

Cost-effectiveness analysis

For both trial arms, the mean values of costs and outcomes are reported, as well as the mean differences between the groups. We used the area under the curve approach, using the trapezium rule, making use of data collected at baseline and 12-month follow-ups to estimate annual costs. Given the skewed distribution of costs, differences in mean costs were compared between the two patient groups using bias-corrected and accelerated (BCa) bootstrapping 1000 times. The primary outcome in the economic analysis is the ICER per QALY gained at 12 months. The ICERs for all analyses were calculated as the mean estimated differences in costs divided by the mean estimated differences in QALYs. Statistical uncertainty was explored through bootstrapping 1000 randomly resampled pairs of costs and outcomes and cost-effectiveness planes generated. These cost-effectiveness planes are graphical displays of cost-effectiveness results plotted on graphs, where the horizontal axis represents the differences in outcomes (QALYs) and the vertical axis represents the differences in costs.

Any results in the north-east quadrant indicate that the intervention costs more but also has greater benefits than the comparator, while observations in the south-east quadrant are considered to be dominant over the comparator as both costs are lower and QALY gains greater. Results in the south-west quadrant show that the intervention costs less but also has fewer QALYs than the comparator, while anything in the north-west quadrant is dominated as the intervention both costs more and has fewer QALY gains than the comparator. The proportions of ICERs falling in each quadrant of the cost-effectiveness plane were calculated, as were the proportions falling underneath the threshold of £20,000 per QALY gained (for results falling in the top right-hand quadrant and the bottom right-hand quadrant). Cost-effectiveness acceptability curves (CEACs) are also generated to show the likelihood of ECHOMANTRA being cost-effective at different willingness-to-pay levels. The primary economic analyses included imputed data for missing values, so as a sensitivity analysis we also conducted additional economic analyses for complete cases only, that is, trial participants with data at baseline and follow-up.

Missing data

Multiple imputation by chained equations was applied to impute missing values for resource use and utility values. The analysis was performed in Stata, and in total, 100 data sets were imputed, taking account of the same factors as reported in *Chapter 3*, as well as age. The costs and outcome analysis models were then run across 100 imputed data sets and combined using Rubin's rules[106] to produce an overall single set of imputed values.

Health economic results

Estimated intervention costs

Mean total intervention cost for ECHOMANTRA was estimated to be £54,873 or £298 per ECHOMANTRA recipient (*Table 26*). Fifty-four per cent of these costs related to the staff time for facilitators, moderators and supervisors of the 271 one-hour-long patient-only, carer-only and joint patient and carer group online sessions, plus some costs associated with the limited number of Skype patients, carers, mentor sessions that did take place before they were instead aligned with the facilitated and moderated online groups in terms of format and scheduling (see *Chapter 1*). In terms of training, we included not only the time of the Band 7 trainers who delivered training over 5 days but also the time costs of both paid staff and volunteers who attended the training. Other costs included workbooks for patient–carer dyads and web-design and hosting costs for the intervention web platform at South London and Maudsley Hospital.

Health service utilisation and hours of productivity loss

There were no significant differences between the ECHOMANTRA and TAU-only groups in any category of health service utilisation at baseline (*Table 27*) using the imputed data set. No economic data at baseline or at 12-month follow-up were available for one individual in the TAU group, meaning the economic analysis is based on 369 rather than 370 study participants. At baseline, approximately half of the previous 3 months had been spent in inpatient care, nearly of all of which was in specialist eating disorder units. Mean all inpatient stay in the two groups respectively were 48.34 and 43.86 nights in the 3 months to baseline [mean difference 4.48 nights (95% CI −2.02 to 11.31; $p = 0.193$)]. The ECHOMANTRA and TAU-only groups reported a mean of 7.55 and 9.41 days as eating disorder unit day patients

TABLE 26 ECHOMANTRA intervention costs £'s 2022 prices

Description	Cost
Group session delivery costs	
Facilitation of 271 group patient-only, carer-only or patient/carer group sessions (Band 5)	11,382
Moderation of group patient-only, carer-only or patient/carer group sessions by volunteers	1287
Moderation of group patient-only, carer-only or patient/carer group sessions by paid staff (Band 5)	5691
Preparation and facilitation of 27 Skype patient, carer and mentor sessions	1701
Supervision/feedback for all group sessions (mean time per session 30 minutes) (Band 7)	9553
Total group session costs	29,614
Training costs	
Band 7 delivered training for 5 training days 5.5 hours' training time for 16 individuals (5 Band 5 and 11 unpaid volunteers)	1939
Band 5 Trainee training session time costs	1155
Band 5 Trainee training session time costs	575
Total training costs	3669
Other costs	
Workbooks	4600
VIMEO video hosting, sharing and services platform	757
Web-design and platform maintenance/hosting	16,234
Total other costs	21,591
Total costs	54,873
Cost per trial participant in ECHOMANTRA + TAU group	298

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TABLE 27 Mean difference in service utilisation per participant at baseline (previous 3 months) (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Health service utilisation, M (SD)				
Eating disorder inpatient stay (nights)	45.64 (32.59)	40.67 (32.46)	4.97 (−1.46 to 11.59)	0.144
General inpatient psychiatric stay (nights)	0.67 (4.36)	1.98 (9.16)	−1.31 (−2.90 to 0.15)	0.111
Other inpatient stay (nights)	2.03 (7.89)	1.21 (3.73)	0.82 (−0.37 to 2.23)	0.218
Eating disorders day patient visits (days)	7.55 (16.66)	9.41 (19.06)	−1.86 (−5.66 to 1.71)	0.305
Hospital outpatient visits (visits)	2.32 (4.42)	2.32 (5.17)	0.00 (−1.01 to 1.00)	0.996
A&E/minor injury clinic (visits)	0.60 (1.05)	0.49 (0.92)	0.12 (−0.07 to 0.32)	0.262
GP (contacts)	2.38 (4.47)	3.26 (7.73)	−0.88 (−2.23 to 0.30)	0.212
GP practice nurse (contacts)	3.89 (13.58)	5.06 (14.15)	−1.17 (−4.26 to 1.78)	0.441
Dietician (contacts)	7.04 (12.49)	7.99 (13.60)	−0.95 (−3.72 to 1.86)	0.484
Dentist (contacts)	0.34 (0.82)	0.38 (1.03)	−0.04 (−0.22 to 0.16)	0.668
Other services (contacts)	1.93 (8.41)	2.54 (11.66)	−0.61 (−2.76 to 1.37)	0.605
All inpatient stays (nights)	48.34 (32.61)	43.86 (32.95)	4.48 (−2.02 to 11.31)	0.193
All A&E/day patient/outpatient (contacts)[b]	10.47 (17.20)	12.22 (20.00)	−1.74 (−5.65 to 1.83)	0.370
All community service (contacts)	15.59 (20.57)	19.24 (26.42)	−3.65 (−8.78 to 1.40)	0.177
Productivity loss (hours)	127.92 (180.46)	137.53 (185.76)	−9.62 (−46.97 to 28.80)	0.617

A&E, accident and emergency.
a Bias-corrected and accelerated bootstraps.
b Each day patient stay assumed to be one contact.

[mean difference -1.86 days; (95% CI −5.66 to 1.71; p = 0.305)]. At 12-month follow-up, there were few significant differences in reported health service resource use over the previous 3 months (*Table 28*). Eating disorder inpatient stays were lower in both the ECHOMANTRA + TAU and TAU groups than seen at baseline; 15.68 versus 14.23 nights, respectively [mean difference 1.45 nights (95% CI −4.09 to 6.89; p = 0.588)], while overall inpatient stays were 19.57 and 16.94 nights, respectively [mean difference 2.62 nights (95% CI −3.06 to 8.74; p = 0.348)]. There was a greater number of contacts with GP practice nurses [mean difference 3.15 contacts (95% CI 0.80 to 5.80; p = 0.010)] and dentists [mean difference 0.48 contacts (95% CI 0.01 to 0.18; p = 0.013)] in the ECHOMANTRA + TAU group at 12-month follow-up. The number of contacts with other community services also increased, but descriptions of these services were largely absent from CSRI responses.

There were also no significant differences in mean hours of productivity loss between the ECHOMANTRA + TAU and TAU groups at baseline or 12-month follow-up. At baseline, there was a mean of 127.92 hours of productivity loss in the ECHOMANTRA group compared with 137.53 in the TAU group [mean difference −9.62 hours (95% CI −46.97 to 28.80; p = 0.617)]. At 12-month follow-up, there was a mean of 64.12 hours of productivity loss in the ECHOMANTRA group compared with 72.03 in the TAU group [mean difference −7.90 hours (95% CI −32.01 to 19.24; p = 0.551)].

Health service costs

There were no differences between the ECHOMANTRA and TAU-only groups either in overall health service costs or any category of healthcare costs using imputed values for missing data at baseline (*Table 29*). Total healthcare costs were £33,695 versus £31,767 in the ECHOMANTRA and TAU groups [mean difference £1928 (95% CI −£1703 to £5522; p = 0.351)]. Eighty-nine per cent (ECHOMANTRA) and 87% (TAU) of total costs were due to inpatient stays in the two groups, respectively.

There were also no differences between the ECHOMANTRA + TAU and TAU-only groups either in overall health service costs using imputed values for missing data at 12-month follow-up (*Table 30*). Total healthcare costs were lower for both groups: £14,322 versus £12,921 in the ECHOMANTRA and TAU groups [mean difference £1401 (95% CI −£1889 to £4855; p = 0.452)]. Eighty-three per cent (ECHOMANTRA) and 81% (TAU) of total costs were due to inpatient stays in the two groups, respectively. At 12-month follow-up, there were significantly greater costs for GP practice nurses [mean difference £27 (95% CI £7 to £52; p = 0.031) Cohen's d = 0.26] and dentists [mean difference £25 (95% CI £9 to £43; p = 0.031) Cohen's d = 0.27] in the ECHOMANTRA group at 12-month follow-up. However, these services combined accounted for < 1% of total costs.

Productivity losses and out-of-pocket expenses

The value of productivity losses at baseline and 12-month follow-up did differ between the two groups; this reflects differences in the opportunity costs of lost wages (*Tables 31* and *32*). Productivity losses reduced in both groups. Baseline: ECHOMANTRA £2947, TAU £3864 [mean difference −£947 (95% CI −£1727 to −£111; p = 0.031)], and 12-month follow-up: ECHOMANTRA £1938 TAU £2653 [mean difference −£715 (95% CI −£1479 to −£111; p = 0.049)]. However, when adjusted for baseline difference, there was no significant difference in the value of productivity losses at 12-month follow-up between the two groups [mean difference £233 (95% CI −£575 to £1157; p = 0.567)]. *Tables 31* and *32* also indicate that there were no differences in overall out-of-pocket expenses between the two groups at baseline and 12-month follow-up. Baseline: ECHOMANTRA £737, TAU £317 [mean difference £420 (95% CI −£23 to £1086; p = 0.318)], and 12-month follow-up: ECHOMANTRA £244, TAU £252 [mean difference −£8 (95% CI −£88 to £75; p = 0.824)]. There were no significant differences in any category of out-of-pocket expenses.

Outcomes: utility and quality-adjusted life-years

The primary health economic outcome was QALYs gained over 12 months, estimated using the EQ-5D-3L. Mean EQ-5D scores in each intervention group at both baseline and 12-month follow-up are reported in *Table 45*. At baseline,

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TABLE 28 Mean difference in service utilisation per participant at 12-month follow-up (previous 3 months) (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Health service utilisation, M (SD)				
Eating disorder inpatient stay (nights)	15.68 (26.32)	14.23 (26.00)	1.45 (−4.09 to 6.89)	0.588
General inpatient psychiatric stay (nights)	1.92 (5.43)	1.59 (7.17)	0.33 (−1.09 to 1.58)	0.671
Other inpatient stay (nights)	1.96 (5.14)	1.12 (3.25)	0.84 (−0.35 to 1.71)	0.074
Eating disorders day patient visits (days)	1.30 (3.60)	2.18 (8.47)	−0.89 (−2.30 to 0.33)	0.236
Hospital outpatient visits (visits)	4.08 (5.97)	5.25 (8.59)	−1.16 (−2.77 to 0.33)	0.129
A&E/minor injury clinic (visits)	0.47 (1.05)	0.41 (0.86)	0.07 (−0.12 to 0.26)	0.551
GP (contacts)	1.69 (2.40)	2.23 (3.28)	−0.55 (−1.13 to 0.02)	0.066
GP practice nurse (contacts)	7.20 (13.89)	4.06 (10.03)	3.15 (0.80 to 5.80)	0.010
Dietician (contacts)	5.19 (9.62)	3.57 (8.19)	1.62 (−0.36 to 3.52)	0.084
Dentist (contacts)	1.00 (2.31)	0.52 (1.01)	0.48 (0.01 to 0.18)	0.013
Other services (contacts)	4.83 (8.81)	8.1 (19.49)	−3.27 (−6.51 to −0.49)	0.05
All inpatient stays (nights)	19.57 (27.17)	16.94 (27.39)	2.62 (−3.06 to 8.74)	0.348
All A&E/day patient/outpatient (contacts)[b]	5.85 (7.22)	7.83 (12.64)	−1.98 (−4.28 to 0.04)	0.086
All community service (contacts)	19.91 (21.82)	18.48 (26.10)	1.43 (−3.85 to 6.47)	0.572
Productivity loss (hours)	64.12 (120.40)	72.03 (129.20)	−7.90 (−32.01 to 19.24)	0.551

A&E, accident and emergency.
a Bias-corrected and accelerated bootstraps.
b Each day patient stay assumed to be one contact.

TABLE 29 Mean difference in health service costs per participant at baseline (previous 3 months) £'s 2022 prices (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Health service costs, M (SD)				
Eating disorder inpatient stays	29,435 (20,955)	26,232 (20,938)	3203 (−899 to 7514)	0.144
General inpatient psychiatric stays	316 (2046)	930 (4297)	−614 (−1380 to 14)	0.103
Other inpatient stays	389 (1248)	455 (1328)	−66 (−339 to 213)	0.605
Eating disorders day patient visits	1970 (4349)	2456 (4974)	−486 (−1330 to 472)	0.308
Hospital outpatient visits	545 (1039)	545 (1216)	0 (−219 to 198)	0.998
A&E/minor injury clinic	183 (318)	148 (278)	35 (−21 to 92)	0.238
GP	100 (188)	137 (325)	−37 (−94 to 10)	0.205
GP practice nurse	34 (118)	44 (123)	−10 (−36 to 15)	0.425
Dietician	704 (1249)	799 (1359)	−95 (−378 to 177)	0.504
Dentist	18 (44)	20 (55)	−2 (−12 to 8)	0.681
All inpatient stays	30,140 (20,893)	27,617 (20,928)	2523 (−1513 to 6721)	0.252
All A&E/day patient/outpatient	2699 (4466)	3149 (5, 179)	−450 (−1329 to 481)	0.352
All community service	856 (1258)	1001 (1429)	−145 (−416 to 121)	0.330
All health services	33,695 (19,130)	31,767 (19,227)	1928 (−1703 to 5522)	0.351

A&E, accident and emergency.
a Bias-corrected and accelerated bootstraps.

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TABLE 30 Mean difference in health service costs per participant at 12-month follow-up (previous 3 months) £'s 2022 prices (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Health service costs, M (SD)				
Eating disorder inpatient stays	10,114 (16,979)	9177 (16,773)	938 (−2288 to 4184)	0.619
General inpatient psychiatric stays	901 (2546)	746 (3364)	155 (−495 to 717)	0.635
Other inpatient stays	862 (1721)	559 (1437)	303 (−10 to 602)	0.069
Eating disorders day patient visits	338 (940)	569 (2211)	−231 (−602 to 108)	0.208
Hospital outpatient visits	959 (1404)	1233 (2018)	−273 (−649 to 60)	0.131
A&E/minor injury clinic	143 (322)	123 (263)	20 (−39 to 86)	0.511
GP	71 (101)	94 (138)	−23 (−47 to 13)	0.062
GP practice nurse	62 (120)	35 (87)	27 (7 to 52)	0.031
Dietician	519 (961)	357 (819)	162 (−26 to 345)	0.073
Dentist	53 (123)	28 (54)	25 (9 to 43)	0.031
All inpatient stays	11,877 (17,224)	10,482 (17,338)	1396 (−1934 to 4653)	0.469
All A&E/day patient/outpatient	1441 (1761)	1926 (3146)	−485 (−1026 to 35)	0.078
All community service	706 (1027)	514 (882)	192 (−19 to 398)	0.056
All health services	14,024 (17,654)	12,921 (17,829)	1103 (−2423 to 4524)	0.559
All health services plus intervention costs	14,322 (17,654)	12,921 (17,829)	1401 (−1889 to 4855)	0.452

A&E, accident and emergency.
a Bias-corrected and accelerated bootstraps.

TABLE 31 Mean difference in productivity costs and out-of-pocket expenses per participant at baseline (previous 3 months) £'s 2022 prices (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Cost, M (SD)				
Productivity losses	2917 (3473)	3864 (4672)	−947 (−1727 to −111)	0.031
Direct expenses, for example, clothes, special or extra food	284 (1505)	188 (331)	96 (−49 to 309)	0.456
Employing extra help, for example, child care	342 (4016)	10 (84)	333 (−255 to 920)	0.438
Over-the-counter medication expenses	18 (76)	13 (27)	5 (−4 to 17)	0.507
Travel expenses to treatment sessions	62 (180)	60 (112)	2 (−22 to 32)	0.888
Other personal expenses such as cleaning products	35 (74)	48 (202)	−13 (−53 to 14)	0.489
All additional expenses[b]	737 (4319)	317 (469)	420 (−23 to 1086)	0.318
All productivity losses and expenses	3654 (6064)	4181 (4785)	−527 (−1576 to 676)	0.396

a Bias-corrected and accelerated bootstraps.
b Note there are two outliers reporting very high additional expenses in the ECHOMANTRA/TAU group.

TABLE 32 Mean difference in productivity costs and out-of-pocket expenses per participant at 12-month follow-up (previous 3 months) £'s 2022 prices (imputed data set)

Type of contact	ECHOMANTRA/ TAU *N* = 184	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Cost, M (SD)				
Productivity losses	1938 (2943)	2653 (3669)	−715 (−1479 to −34)	0.049
Direct expenses, for example, clothes, special or extra food	155 (301)	165 (317)	−11 (−83 to 58)	0.741
Employing extra help, for example, child care	17 (55)	13 (56)	4 (−7 to 15)	0.487
Over-the-counter medication expenses	19 (31)	18 (29)	1 (−5 to 7)	0.752
Travel expenses to treatment sessions	35 (66)	37 (78)	−2 (−17 to 12)	0.779
Other personal expenses such as cleaning products	19 (32)	19 (37)	0 (−8 to 7)	0.937
All additional expenses	244 (350)	252 (365)	−8 (−88 to 75)	0.824
All productivity losses and expenses	2182 (2971)	2905 (3745)	−722 (−1433 to −50)	0.046

a Bias-corrected and accelerated bootstraps.

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the estimated mean difference between ECHOMANTRA versus TAU in EQ-5D scores was 0.054 (95% CI −0.016 to 0.125) p = 0.110. The results show that mean EQ-5D scores improved over the study period for both trial arms, although the improvements were greater in the TAU group [mean difference −0.001 (−0.067 to 0.060) p = 0.962]. This indicates that compared with the control group, the mean EQ-5D score was higher in the intervention group at baseline, whereas after 12 months the mean EQ-5D scores were similar between the two groups. Based on the EQ-5D scores, at both the baseline and 12-month follow-up, QALYs were calculated. The number of QALYs gained per participant over 12 months in the ECHOMANTRA group was 0.008 (SD 0.317) compared to 0.064 (SD 0.327) in the TAU group [mean difference −0.059 (−0.122 to 0.010); p = 0.097], as QALY gains were slightly higher in the TAU group than in the ECHOMANTRA group.

Cost–utility analysis

In the primary economic analysis from a health system perspective using the imputed data set to account for missing data, the ICER per QALY gained for the use of ECHOMANTRA versus TAU only was calculated. ECHOMANTRA was dominated by TAU in that the former cost more (£5948, 95% CI −£6297 to £17,786) and resulted in fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010) (*Table 34*). When looking at the results from a wider societal perspective, ECHOMANTRA is also dominated by TAU in that the former costs more (£3351, 95% CI −£9253 to £15,371) while resulting in fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010).

Bootstrapped differences in costs and QALYs gained using the imputed data set from a health service perspective are also shown on a cost-effectiveness plane (*Figure 11*). In this figure, incremental changes in QALYs gained are shown on the horizontal axis, and incremental changes in costs on the vertical axis. Seventy-seven per cent of observations are in the north-west quadrant, where ECHOMANTRA has both higher costs and lower QALY gains than TAU. Fourteen per cent of observations fall in the south-west quadrant, where ECHOMANTRA has lower costs but also lower QALY gains than TAU. Eight per cent of observations fall in the north-east quadrant, indicating ECHOMANTRA has higher costs but better QALY gains compared to TAU. Two per cent of observations fall in the south-east quadrant, where ECHOMANTRA has lower costs and better QALY gains.

The information from the cost-effectiveness plane was used to create a CEAC, which shows the likelihood of ECHOMANTRA being cost-effective at a range of values of the cost-effectiveness threshold (*Figure 12*). The horizontal access shows different levels of willingness to pay per QALY gained up to £50,000, with the probability of ECHOMANTRA being cost-effective compared to TAU only shown on the vertical access. The CEAC lies below the 50% region for all thresholds, supporting the conclusion that ECHOMANTRA is dominated by TAU. There is an 11.5% probability of being cost-effective at the standard willingness-to-pay threshold of £20,000 per QALY gained; but in this case, this is mainly for observations that have lower costs but also lower QALY gains rather than for improvements in QALYs.

Bootstrapped differences in costs and QALYs gained using the imputed data set from the wider societal perspective are also shown on a cost-effectiveness plane (*Figure 13*). In this case, 64% of observations are in the north-west quadrant, where ECHOMANTRA has both higher costs and lower QALY gains than TAU. Twenty-seven per cent of observations fall in the south-west quadrant, where ECHOMANTRA has lower costs but also lower QALY gains than TAU. Six per cent of observations fall in the north-east quadrant, indicating ECHOMANTRA has higher costs but better QALY gains compared to TAU. Four per cent of observations fall in the south-east quadrant, where ECHOMANTRA has lower costs and better QALY gains.

The CEAC from this societal perspective is below the 50% region for all thresholds, supporting the conclusion that ECHOMANTRA is dominated by TAU (*Figure 14*). There is a 25% probability of being cost-effective at the standard willingness-to-pay threshold of £20,000 per QALY gained; but again, this is mainly for observations that have lower costs and lower QALY gains rather than for improvements in QALYs.

TABLE 33 Mean EuroQol-5 Dimensions, five-level version scores per participant at baseline and 12-month follow-up and mean QALYs gained (imputed data set)

Time period	ECHOMANTRA/TAU *N* = 184 Mean (SD)	TAU *N* = 185	Mean difference (BCa 95% CI)[a]	*p*-value
Baseline	0.521 (0.317)	0.466 (0.315)	0.054 (−0.016 to 0.125)	0.110
12-month follow-up	0.529 (0.299)	0.530 (0.313)	−0.001 (−0.067 to 0.060)	0.962
QALYs gained	0.008 (0.317)	0.064 (0.327)	−0.059 (−0.122 to 0.010)	0.097

a Bias-corrected and accelerated bootstraps.

TABLE 34 Cost per additional QALY gained health and societal perspectives (imputed data set)

Outcome	ECHOMANTRA/TAU *N* = 184	TAU *N* = 185	Mean difference (95% CI)[a]	*p*-value
Mean values (SD)				
Total health system perspective cost	85,902 (59,758)	79,954 (55,086)	5948 (−6297 to 17,786)	0.315
Total societal perspective cost	96,839 (62,348)	93,488 (59,355)	3351 (−9253 to 15,371)	0.606
QALY change	0.008 (0.317)	0.064 (0.327)	−0.059 (−0.122 to 0.010)	0.097
ICER (cost per QALY gained) (95% CI) health system perspective	Dominated by TAU (Dominated, 549,899)[b]			
ICER (cost per QALY gained) (95% CI) societal perspective	Dominated by TAU (Dominated, 513,355)[b]			

a Bias-corrected and accelerated bootstraps.
b Confidence intervals from 1000 bootstrapped paired samples of costs and outcomes.

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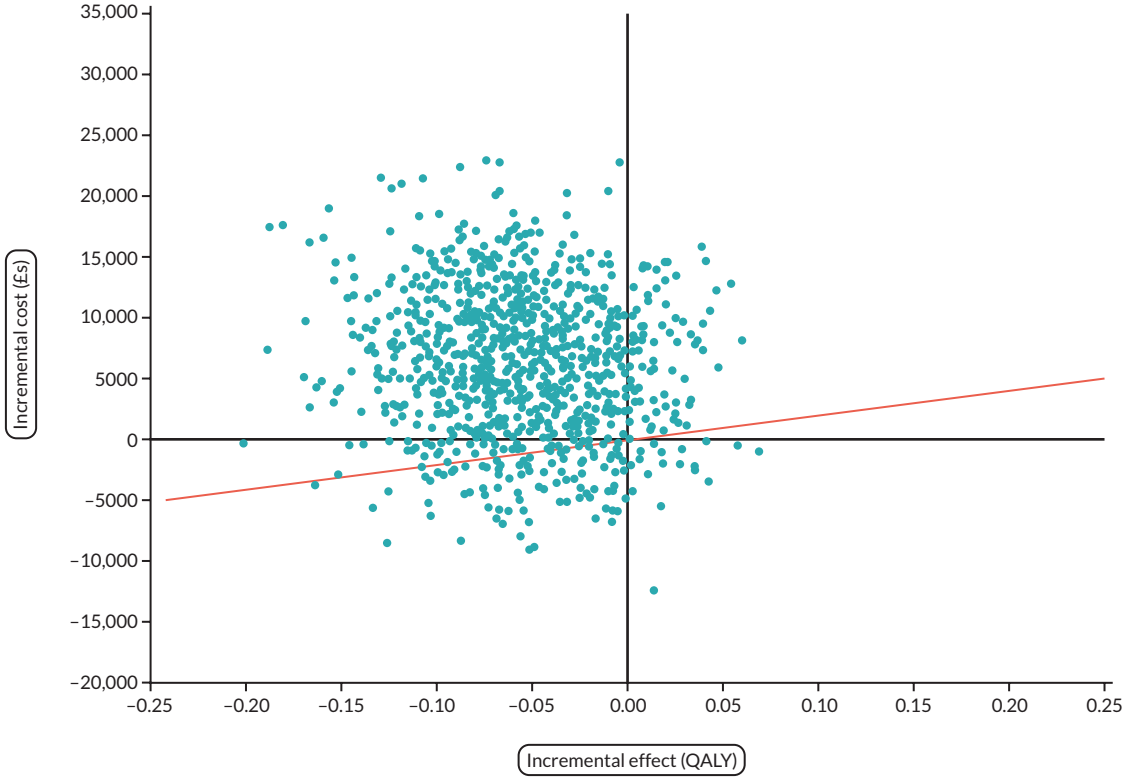

FIGURE 11 Cost-effectiveness plane – health system perspective (imputed data set). Note: Red line represents willingness to pay of £20,000 per QALY gained.

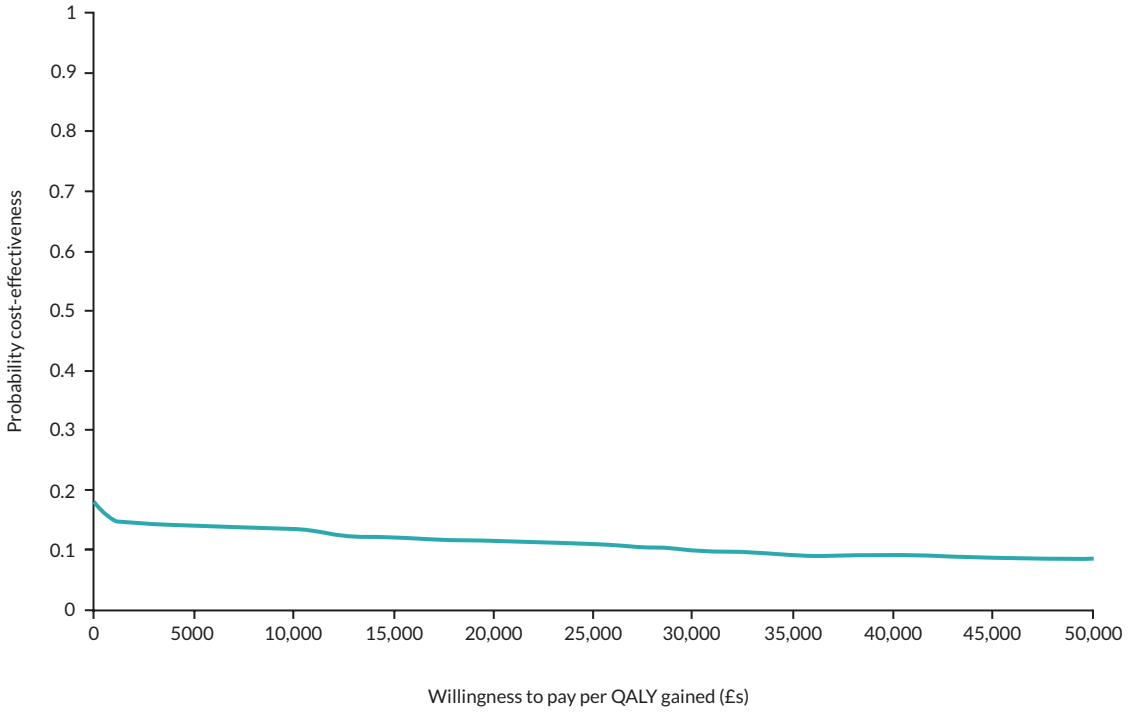

FIGURE 12 Cost-effectiveness acceptability curve health system perspective (imputed data set).

Sensitivity analysis

In order to explore the potential impact of missing data on estimated treatment effects and costs, a sensitivity analysis was conducted based on the complete cases. In this trial, completed costs and EQ-5D-3L data were available for 242 participants (65% of all participants), 108 in the ECHOMANTRA group and 134 in the TAU group. As shown in *Report Supplementary Material 1*, *Tables 1*, *2*, *3* and *4* indicate that there were no significant differences in baseline or 12-month follow-up data for health service utilisation and overall healthcare costs. *Report Supplementary Material 1*, *Tables 5 and 6* indicate there were also no significant differences between the two groups at both time points for productivity losses or in out-of-pocket expenses.

Table 35 shows the ICER for the CCA from both the health system and wider societal perspectives. In this CCA from a health system perspective, ECHOMANTRA had a cost per QALY gained of £37,213. However, while the ECHOMANTRA group had lower costs (−£1912, 95% CI −£17,987 to £12,479), it also resulted in fewer QALYs gained (−0.051, 95% CI −0.137 to 0.034). When looking at the results from a wider societal perspective, ECHOMANTRA had a cost per QALY gained of £78,990. Again, while the ECHOMANTRA group had lower costs (−£4053, 95% CI −£22,546 to £12,497), it also resulted in fewer QALYs gained (−0.051, 95% CI −0.137 to 0.034).

Bootstrapped differences in costs and QALYs gained using the complete-case data set only from a health service perspective are also shown on a cost-effectiveness plane (*Figure 15*). Thirty-five per cent of observations are in the north-west quadrant, where ECHOMANTRA has both higher costs and lower QALY gains than TAU. Fifty-four per cent of observations fall in the south-west quadrant, where ECHOMANTRA has lower costs but also lower QALY gains than TAU. Four per cent of observations fall in the north-east quadrant, indicating ECHOMANTRA has higher costs but better QALY gains compared to TAU. Eight per cent of observations fall in the south-east quadrant, where ECHOMANTRA has lower costs and better QALY gains. The CEAC (*Figure 16*) indicates that there is an 53% probability of being cost-effective at the standard willingness-to-pay threshold of £20,000 per QALY gained for ECHOMANTRA compared to TAU; however, this again is due to the high number of bootstrapped observations that have lower costs and lower QALY gains rather than for improvements in QALYs.

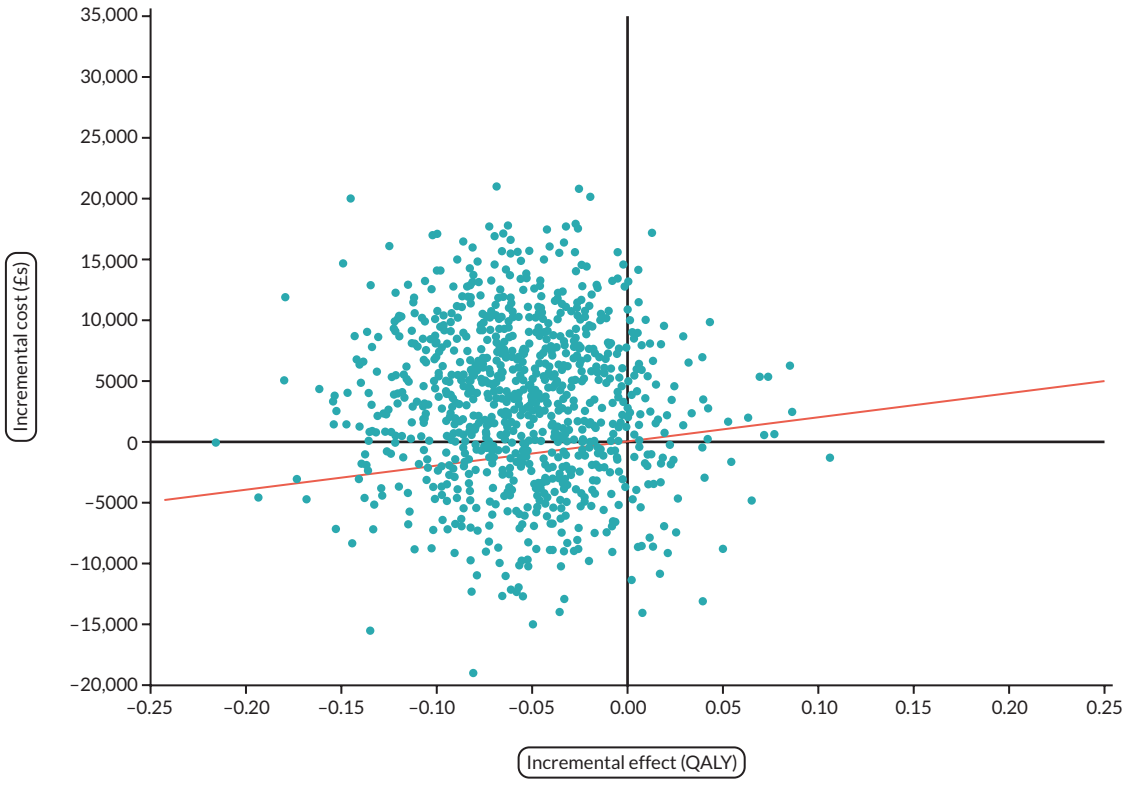

FIGURE 13 Cost-effectiveness plane – societal perspective (imputed data set). Note: Red line represents willingness to pay of £20,000 per QALY gained.

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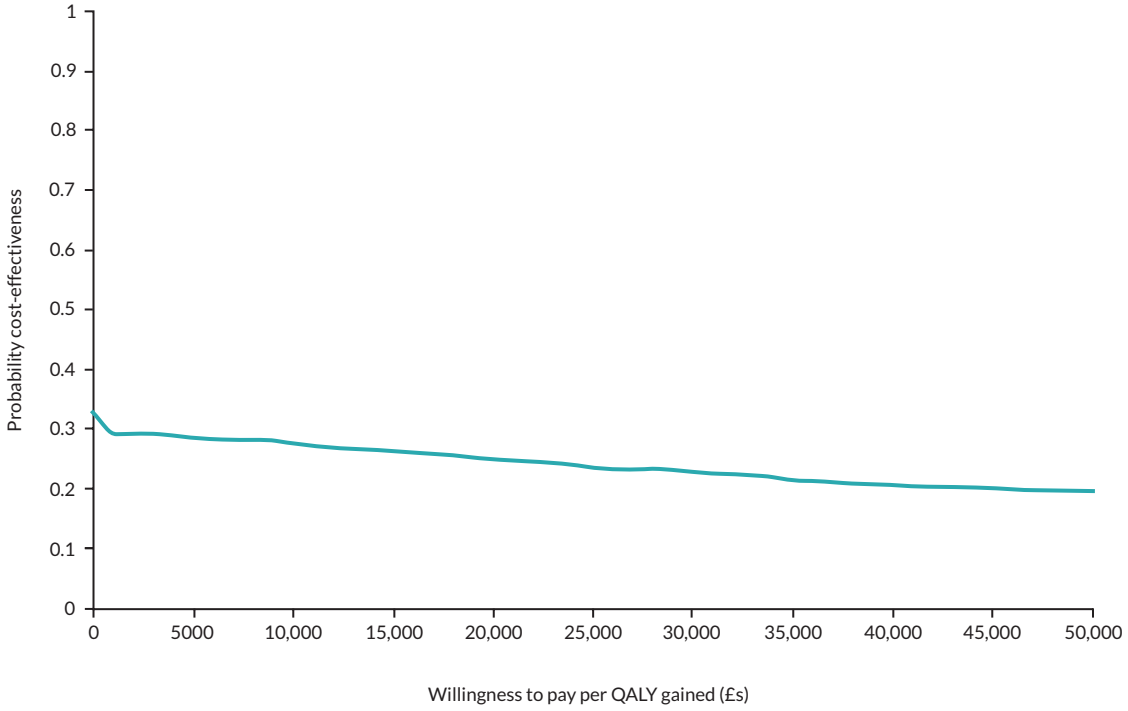

FIGURE 14 Cost-effectiveness acceptability curve, societal perspective (imputed data set).

In respect of the wider societal perspective, bootstrapped differences in costs and QALYs gained using the complete-case data set were also calculated (see *Report Supplementary Material 1*, *Figure 2*). Twenty-eight per cent of observations are in the north-west quadrant, where ECHOMANTRA has both higher costs and lower QALY gains than TAU. Sixty per cent of observations fall in the south-west quadrant, where ECHOMANTRA has lower costs but also lower QALY gains than TAU. Four per cent of observations fall in the north-east quadrant, indicating ECHOMANTRA has higher costs but better QALY gains compared to TAU. Nine per cent of observations fall in the south-east quadrant, where ECHOMANTRA has lower costs and better QALY gains. The CEAC in *Report Supplementary Material 1*, *Figure 3* indicates that there is an 62% probability of being cost-effective at the standard willingness-to-pay threshold of £20,000 per QALY gained for ECHOMANTRA compared to TAU; however, this is due to the majority of bootstrapped observations that have lower costs and lower QALY gains rather than for improvements in QALYs.

Fidelity to intervention delivery potentially may have an impact on cost-effectiveness. In addition to these complete-case sensitivity analysis, we also explored differences in costs for health services, productivity losses and all out-of-pocket expenses at 12-month follow-up, as well as in quality-of-life outcomes, within the ECHOMANTRA group between the 36 patient–carer dyads that had at least 4 online group sessions and the remaining 148 patient–carer dyads who attended fewer sessions. All of these costs were lower for those receiving four or more online sessions, while quality-of-life outcomes and the incremental change in quality of life gained were also greater (*Table 36*). While the sample size is low, future analysis might wish to look at whether it may be cost-effective to invest in measures to increase to fidelity of treatment as part of any further evaluation.

Summary of main results

ECHOMANTRA was dominated by TAU as it cost more (£5948, 95% CI −£6297 to £17,786) and resulted in fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010).

From the societal perspective, ECHOMANTRA was dominated by TAU with higher costs (£3351, 95% CI −£9253 to £15,371) and fewer QALYs gained (−0.059, 95% CI −0.122 to 0.010).

TABLE 35 Cost per additional QALY gained (complete cases only) health and societal perspectives

Outcome	ECHOMANTRA/TAU *N* = 108	TAU *N* = 134	Mean difference (95% CI)[a,b]	*p*-value
Mean values (SD)				
Total health system perspective cost	71,916 (62,639)	73,827 (55,900)	−1912 (−17,987 to 12,479)	0.801
Total societal perspective cost	82,776 (65,947)	86,834 (62,270)	−4053 (−22,546 to 12,497)	0.613
QALYs at 12 months	0.577 (0.293)	0.553 (0.311)	0.024 (−0.054 to 0.103)	0.564
QALY change	0.028 (0.308)	0.079 (0.316)	−0.051 (−0.137 to 0.034)	0.209
ICER (cost per QALY gained) (95% CI) health system perspective	£37,213 (£137,414 to £370,819)			
ICER (cost per QALY gained) (95% CI) societal perspective	£78,990 (£161,795 to £354,680)			

a Bias-corrected and accelerated bootstraps.
b Confidence intervals from 1000 bootstrapped paired samples of costs and outcomes.

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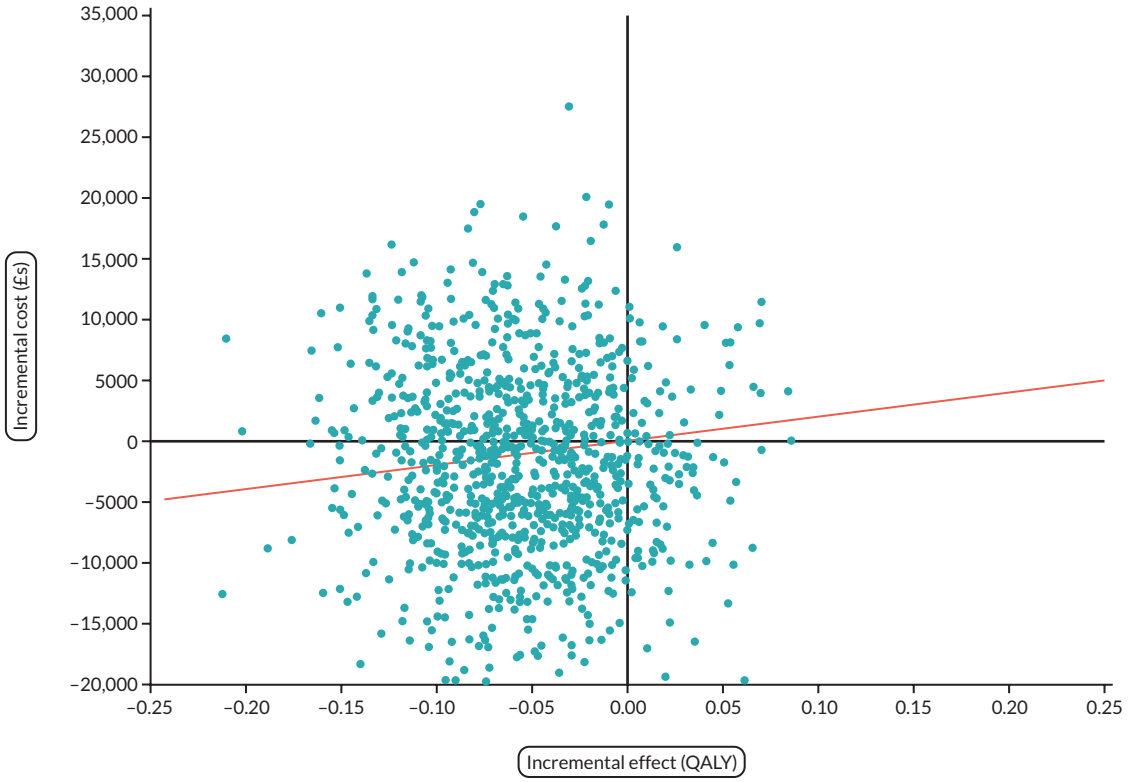

FIGURE 15 Cost-effectiveness plane – health system perspective (complete cases only).

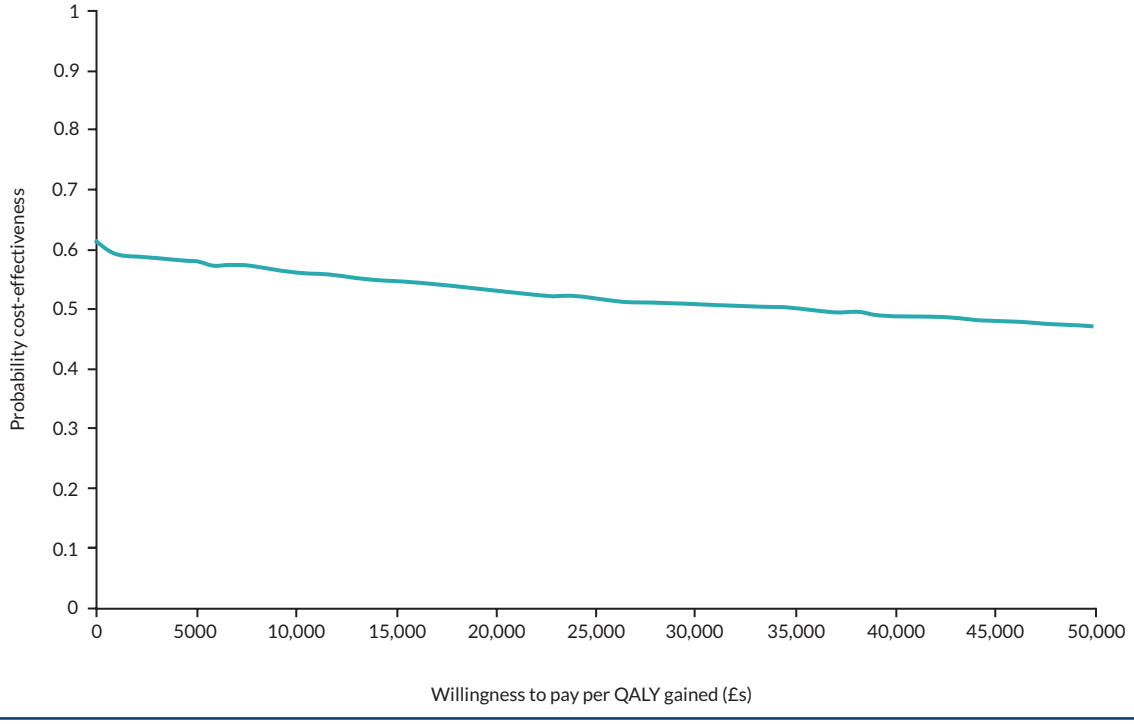

FIGURE 16 Cost-effectiveness acceptability curve health system perspective (complete cases only).

TABLE 36 Comparison of previous 3-month costs at 12-month follow-up and QALYs gained ECHOMANTRA group who did or did not complete at least four online group sessions (imputed data set)

Outcome at 12 months	At least 4 online group sessions *N* = 36	< 4 online group sessions *N* = 148	Mean difference (BCa 95% CI)[a,b]	
	Mean (SD)			*p*-value
All inpatient costs	8163 (18,507)	12,781 (16,839)	−4617 (10,466 to 1564)	0.197
Total health system costs	9791 (19,066)	15,425 (17,181)	−1912 (−17,987 to 12,479)	0.801
Productivity losses	950 (1693)	2178 (3131)	−1228 (−1933 to −478)	0.006
Out-of-pocket expenses	125 (183)	273 (375)	−149 (−235 to −72)	0.002
QALYs at 12 months	0.618 (0.257)	0.501 (0.305)	0.108 (0.007 to 0.196)	0.045
QALY change	0.035 (0.318)	0.001 (0.318)	0.034 (−0.080 to 0.148)	0.195

a Bias-corrected and accelerated bootstraps.
b Confidence intervals from 1000 bootstrapped paired samples of costs and outcomes.

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From the health system and societal perspectives, there is an 11.5% and 25% probability of being cost-effective at a willingness-to-pay threshold of £20,000 per QALY gained. These results were similar for the CCAs.

Client Service Receipt Inventory responses indicated that, overall, all inpatient stays for the previous 3 months reduced in the ECHOMANTRA and TAU groups from a mean 46 nights to 18 nights between baseline and 12-month follow-up. Mean decrease between the two time periods for the ECHOMANTRA group was 28.77 nights versus 26.92 nights for the TAU group [mean difference 1.85 nights (95% CI −10.99 to 6.85; $p = 0.661$)]

Quality of life improved in both groups between baseline and 12-month follow-up by 0.036 QALYs, but QALY gains were greater in the TAU group. ECHOMANTRA 0.008 QALYs, TAU 0.064 QALYs [mean difference −0.059 (95% CI −0.122 to 0.010) $p = 0.097$].

In sensitivity analysis, higher levels of engagement with ECHOMANTRA were associated with lower health service costs, productivity losses and improved quality of life compared with participants with lower levels of engagement. However, only 20% of ECHOMANTRA participants sufficiently adhered to the ECHOMANTRA approach, and further research could explore whether actions that improve engagement improve its cost-effectiveness.

Chapter 5 Process evaluation

Introduction

The overall goal of this section is to describe three studies which investigated patients' and carers' experiences of transitioning from intensive hospital treatment back into the community (Study 1) and their experience of the ECHOMANTRA intervention, with a focus on suggestions for improvement (Study 2). In Study 3, we discuss the factors that prevented or promoted usage of the intervention.

Study 1: A qualitative investigation of the experiences and needs of adults with anorexia nervosa and their carers during treatment transition from inpatient or day patient care

The overall goal of this study, described in depth elsewhere[13] and summarised below, was to explore patients' and carers' experiences of transitioning from specialist, intensive eating disorder treatment settings back into the community.

Methods

Participants

Chapter 2 provides a description of the eligibility criteria of participants enrolled in the trial. Among those, participants who had been randomised to the TAU arm of the study for a minimum of 6 months were invited to participate in this study.

Interviewers

Research assistants with lived experience of the illness (DCB, KR) and a postdoctoral researcher with lived experience of caring (PM) drew upon their experiential knowledge in addition to their academic experience in both the development and later analysis of the interviews.

Interview schedules

Semistructured interview schedules were developed iteratively through discussion between members of the TRIANGLE research team (JT, VC, DCB, KR, PM). The interview schedule for the TAU participants consisted of questions around both the challenges experienced, and support received, following discharge from hospital. For example, patient participants were asked, 'After leaving intensive treatment, what support did you receive?'; 'What challenges, if any, did you face upon discharge?'; 'What suggestions do you have for a seamless transition process?'. Carers were asked either identical or similar questions, for example: 'After leaving intensive treatment, what support did your loved one receive?'; 'What challenges, if any, did you face upon discharge in supporting your loved one?' (for the full interview schedule, see *Appendix 8*).

Interview procedure

Trial participants who had been randomised for a minimum of 6 months to the TAU arm of the trial were sent an e-mail invitation to be interviewed about their experience of transitioning from hospital to home. Participants who replied were scheduled in for interviews on a first-come, first-serve basis until data saturation was reached. The interviews were conducted by an eating disorders researcher (PM) who was independent from the participant-facing TRIANGLE team and had no prior direct contact with the participants. All interviews were undertaken during the first COVID-19 lockdown period between April and October 2020. Participants were interviewed individually via Skype teleconference due to the COVID-19 restrictions that were in place. Each interview lasted between 45 and 90 minutes.

Data analyses

All interviews were completed, transcribed and coded before the main trial outcome data analyses were conducted. All interviews were audio-recorded using Skype for Windows desktop and were transcribed verbatim. Personal identifying

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information was removed. Thematic analysis was used to analyse the data (Braun and Clark 2006).[107] Two researchers (PM and DCB) read the transcripts several times, independently. They then coded, reviewed and finalised 'utterances' and developed an initial thematic framework using NVivo for Mac [QSR International, Warrington, UK (released in March 2020). 2020]. Emerging patterns were discussed until data saturation and initial analyses were shared for feedback with the larger team. Themes and subthemes were finally established.

Results

Participant characteristics

Thirty-one participants were recruited into the study, including 11 patients and 20 carers, of which eight were patient–carer dyads (i.e. belonged to the same family). Participants were recruited from 13 different specialist eating disorder units involved in the TRIANGLE trial.

Patients were young adults with an average age of 24.78 (SD = 7.99). All patients were white. As expected, all patients had severe AN when they joined the trial, marked by a low BMI (M = 16.77, SD = 2.14) and a long duration of illness (M = 8.35, SD = 8.20 years). When not in hospital, patients lived with their parents (*n* = 15), partner (*n* = 3), in a university accommodation (*n* = 1), or alone (*n* = 4). The average age of carers was 54.05 (SD = 8.15), of whom all were white, mostly female (*n* = 16, 80%) and mostly mothers (*n* = 16, 80%), although one father and three partners (from heterosexual relationships) also took part.

The results from the thematic analysis reported here are based on the results section of the publication.[13]

Patient themes

Four themes emerged from the patient data set: continuity of care, ambivalence about continued recovery, the value of social support and a call for enhanced aftercare support.

Continuity of care

Patients gave accounts of the type of professional support they received following intensive treatment and highlighted how continuity of this care (or lack of it) affected their recovery. All described their experiences of post-discharge treatment and care, which varied from phased day care with specific treatment plans to less structured support.

> *I saw a therapist down at my local eating disorder service once a week [after discharge]. Being able to have access to a therapist at home was definitely helpful [and] I managed to get back into a routine.*
>
> *Patient 2*

Six patients described problematic post-discharge care experiences. Typical issues included a perceived lack of communication and/or continuity between the services, premature/rushed discharge and little or no support offered.

> *We weren't given anything [after discharge] … they said, 'all right, we'll refer you to the community out-patient team' and put me back on a waiting list which is 2 years long.*
>
> *Patient 6*

Patients emphasised the personally challenging aspects of the transition period. A lack of structure and support, and increased responsibility for one's own well-being, were particularly challenging. Concerns about managing weight and food intake were cited as frequent personal challenges.

> *They did the weight restoration … but they didn't fix my mind so as soon as I was back home the old habits just kicked straight back in and now I'm finding it a struggle, a real, real struggle.*
>
> *Patient 3*

Ambivalence about continued recovery

This theme reflects the complex and often conflicting attitudes and feelings that patients experienced during the transition period. On the one hand, patients described increased motivation and autonomy in recovery, eloquently expressing insights into their illness and obstacles to recovery; but on the other hand, they described a continued struggle with change. Across all interviews, patients demonstrated self-efficacy, autonomy and motivation. Several patients returned to work or began volunteering, whereas others practised mindfulness or other activities to maintain a sense of routine and purpose. The importance of nurturing social networks was also discussed as a motivating factor.

> *I don't like the fact I was put in hospital and I had to put my life on hold. I've got a lot of friends, I've got things I need to get done so the threat of if I have to go back [to hospital] … then I would be set back even further.*
>
> *Patient 10*

Just over half of the patients evidenced personal insights into the illness that they had gained during intensive treatment and upon returning home.

> *It's harder now than it was when I was in the throes of anorexia. Back then I felt numb and powerful and now I feel vulnerable and angry and out of control, but I'm determined … but I'll be totally honest, if I really need to be I can be very deceitful.*
>
> *Patient 6*

Approximately half of the patients reported continued persistent challenges and obstacles regarding eating-disorder-related thoughts and behaviours, including non-adherence with treatment, frustration at the enduring nature of an eating disorder and remaining in the pre-contemplation or contemplation phase of the illness.

> *I feel trapped between an absolute constant, constant fear of gaining, a constant desire for losing weight, a constant feeling that I'm too big and I want to get smaller.*
>
> *Patient 3*

The value of social support

Almost all of the patients interviewed expressed some appreciation and acceptance of carer involvement during the transition period. Examples given included being accompanied to appointments; help with meal planning, shopping and meal support; and a sense of being understood as an individual with an illness.

> *I definitely couldn't do it without my mum. I'm very fortunate in that she wants to be actively involved in my recovery.*
>
> *Patient 5*

Patients expressed specific views on support offered to carers. Although some felt that their carers had benefited from accessing information and support from services or carer support groups, others believed the psychoeducation provided was irrelevant to their own situation (particularly after multiple admissions or because of a severe and enduring form of eating disorder).

> *I think the effect on family is quite significant … there was a parent support network at the hospital that I was in for inpatients, and they said that was quite helpful.*
>
> *Patient 1*

Several patients expressed understanding and empathy for the carer role, acknowledging the difficulties encountered in supporting them, particularly in relation to deceptive behaviour. One patient discussed the challenges her partner faced in providing eating disorder support.

> *There's a fine line between them being your carer and your husband … I'd love him to have somebody [to support him], probably a male, I feel like that would be easier for him.*
>
> *Patient 6*

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However, three patients spoke candidly of a complete lack of carer support, citing unhelpful involvement perceived as detrimental to their well-being and recovery, or complete disengagement by family members.

> *Before I went into hospital, I decided to move out of my mum's house because she was very toxic, and she told me that I wasn't ill.*
>
> *Patient 10*

Several patients also spoke of the benefits of peer support, both for themselves and their carers, such as feeling emotionally supported and providing respite for the family. Types of peer support included informal links with other patients, organised peer groups and carer support networks.

> *I've got people who used to go to the service with me who I've got in contact with. We're struggling with the same kind of thing, so that's really helpful having that support.*
>
> *Patient 8*

A call for enhanced aftercare support

The majority of patients highlighted the importance and usefulness of a phased, supportive approach to transitions. This included the suggestion of a longer-term programme with the patient taking increasing responsibility for mealtimes and self-care to create a smoother transition home. Being able to maintain some contact with their treatment team when reducing intensive support was felt to create a more secure environment for patients to progress with their recovery.

> *I feel it's a process that you need to go through with a key worker or a therapist or whatever, just to walk you through it and make sure you're actually ok with the stepping-down process and the discharge process … because it is such a big deal.*
>
> *Patient 11*

Half of the patients called for more inclusive support tailored to individual needs as opposed to a one-size-fits-all system. For example, an individual questioning their sexuality and gender identity and an individual with autism felt that they would have benefited greatly from a more personalised eating disorder treatment plan that addressed issues related to identity and comorbidities and allowed appropriate support to be put in place at home before discharge.

> *They need a far bigger approach so that eventually people like myself can actually have a tailored approach … because [otherwise] it has disastrous consequences for people like myself.*
> *Patient 4*

Finally, several patients advocated greater co-ordination and continuity between services. Suggestions included improved communication between treatment teams, with the aim of having better informed staff, and continuity so that trust and therapeutic alliances built during their treatment could be nurtured.

> *I think there needs to be more accommodations between inpatient and out-patient treatment professionals consistently so that when you're discharged, it's not just on the patient to try and figure out what we need … because I don't think we always know what we need.*
>
> *Patient 5*

Carer themes

Four themes emerged from the carer data, including the impact of the eating disorder on themselves and the family, perceptions of recovery and support post discharge, the impact of previous treatment and care experiences, and the desire to create a supportive transition process.

Impact of the eating disorder on themselves and the family

Challenges to carers' mental and physical health were discussed by nearly all carers as they reflected on what it felt like to live with uncertainty over the future of their loved ones as well as experiencing isolation, blame, stigma, exhaustion, apathy, frustration, guilt, fear, anxiety and depression. Some carers reflected on their maladaptive coping mechanisms, such as overusing alcohol. Others expressed confusion about the nature of the illness and how to respond to it.

> *The effect really is quite catastrophic actually on my own physical and mental health. It's the first time I've ever had to approach a GP [general practitioner] with regards to my mental health.*
>
> *Carer 1*

Carers highlighted the skills, strength and coping mechanisms they used to address these challenges and bolster their strength to continue their role. Some carers sought out skills training programmes or psychoeducational books, or independently implemented adaptive cognitive mechanisms to cope with their situation. Participation in hobbies or their faith were described as acts of self-care. Several carers also engaged with their own therapist or consulted their GP. There were also several references to carers' persistent, unfailing support, hope and resilience that built up in the face of adversity.

> *I just think it's really important to engage more … we bought lots of books and we learned things through the carers support group meetings, and we read quite a lot …*
>
> *Carer 3*

Half of the sample spoke about the negative impact on relationships because of differing opinions on how to address the eating disorder within the family unit. Some partners spoke of their unique worries and the challenges faced in their relationships, and parents also highlighted concerns about the impact of AN on the well-being of siblings.

> *I try to be supportive but it does put a stress on a marriage … we have different approaches and different ways of thinking. I've noticed that one of the things that happens is that you tend to blame each other as a way of coping … which is wrong really.*
>
> *Carer 10*

The practical demands on, and challenges for, carers were referenced by nine carers. Carers experienced many logistical challenges, such as the timing or location of skills training courses, and struggling to arrange home leave with their loved one in a hospital far away. Some carers had given up work to care for their loved one, and others expressed guilt at having to juggle several responsibilities, such as child care and work, alongside supporting their loved one.

> *… trying to make sure whilst she was going out and about that she was eating properly. That was quite difficult to manage because I wasn't watching her 24/7, so I had to give her responsibility, but she wasn't really ready for it.*
>
> *Carer 7*

Perceptions of recovery and support post discharge

This theme reflects the complex array of factors that carers perceived to have supported or inhibited continued recovery during the transition period. Seventeen carers conveyed perceptions of receiving inadequate post-discharge support, both for the patient and the family. Reasons included lack of resources, little or no treatment planning, and lack of co-ordination and continuity between the services. Carers perceived that this was inadequate for their loved one's continued recovery, and sometimes even harmful.

> *It's like none of the treatment happened at all and I think this is such a poor finish to it after all the work they've done with her … not to have some continuity or concrete plan in place … because she's not had the support. The support's been awful.*
>
> *Carer 20*

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Seventeen carers spoke about the availability of post-discharge support, including telephone calls from therapists or nurses in the context of outpatient/day care as well as support from other professionals, such as dieticians and local GPs. Carers gave several positive accounts of discharge planning having taken place when their loved one was still an inpatient, and of support offered to carers during the transition period.

> *I have a therapist from the eating disorder team who calls me once a week to offer support and talk through things, you know 'How has the week been?', which has been very helpful.*
>
> *Carer 11*

Most carers also referred to transition challenges and perceived relapse, citing concern around witnessing their loved one's deterioration in well-being. Carers reported noticing signs of eating-disorder-related thoughts and behaviours, weight loss, negative moods and isolation that specifically occurred during the transition period.

> *She's gone back to being very snappy sometimes and she's gone back to being very in control of what everyone's eating in the house.*
>
> *Carer 14*

Nevertheless, more than half of the carers made a point of highlighting perceived signs of improvement in their loved ones along with patient efficacy, for example, engaging in activities, work, study or social life. There were also some reports of improved communication between carers and patients, which facilitated easier carer support and improved relationships.

> *For instance, today he decided that he was going to sit down and have a cup of tea and try and write something in a journal or do some Headspace [meditation app] or just try and relax for half an hour.*
>
> *Carer 12*

The impact of previous treatment and care experiences

Carers recounted experiences of care that were relevant to how their loved ones managed post discharge. These included positive experiences of care provided (e.g. GP care, early diagnosis and/or inpatient treatment).

> *She had out-patient care every week with the psychiatrist … there was lots of continuity there. It was actually fantastic, to be honest.*
>
> *Carer 19*

More than half of the sample reported experiences of multiple admissions and non-adherence, including refusal of treatment or self-discharge.

> *Well, she was in for 9 months at [in-patient unit], the previous year she was 9 months in [in-patient unit] and that sort of broke down as well …*
>
> *Carer 20*

Half of the carers perceived problematic inpatient care, such as disagreements with aspects of the care pathway or the legal framework for care of eating disorders, and challenging relationships with key team members.

> *Unfortunately, her experience in the residential unit was not a good experience and I feel very much that her mental health was compromised during that time although her physical health improved, her mental health deteriorated.*
>
> *Carer 3*

Several carers spoke of alternative treatment sought outside the mainstream NHS. These were either alternative therapies or private care, with one carer opting for specialist AN treatment outside the UK.

> *He liaised with the GP and then also with the non-eating disorder psychiatrist who was looking after him … that made a massive improvement but that would not have happened if we hadn't tried to get private [help].*
>
> *Carer 10*

Desire to create a supportive transition process

Carers provided considerable insight into their own needs and those of their loved ones during the entire process, from intensive treatment through the transition period. Many expressed the need for expert carer support and information. This included improved signposting concerning where to obtain specialist information from service providers or support groups, and skills training for carers. The need for individually tailored guidance for male carers and patients was also emphasised.

> *As a male, you can be maybe a bit more direct or pointed, or a bit deeper pitched, so there's that perception that you're aggressive or angry … I always felt there's not much out there for blokes.*
>
> *Carer 18*

Many of the responses reflected a desire for greater inclusion in the recovery process. Some carers felt excluded, either within their own family unit (e.g. one parent feeling less involved and helpful than another) or by the service and professionals.

> *She's a young adult and I know they have to be really careful about how they engage with families … but she was not going anywhere other than coming home so I think it's really important to engage more with families to get them on board.*
>
> *Carer 3*

Over half of the carers interviewed reflected the positive benefits of social support and peer groups. There were several references to the usefulness of support from partners, other children, extended family or friends. Peer group support (in person or online) was also valued because carers could identify with others who encountered similar challenges.

> *I've got a couple of really good friends who kept checking in on me, the way you want the service to check in on you … obviously I talk to my husband but you are living, breathing it together. You just want to offload it somewhere.*
>
> *Carer 8*

Over half of the sample gave suggestions for improving the transition process that were substantiated by aspects of care they felt they had lacked or had found helpful. Most suggestions included phased or tiered transition and a sense of continuity from inpatient treatment to home.

> *I think that there almost needs to be some step-down process … there would be some support and they would be enabled to support themselves in terms of managing and cooking, all of that sort of thing.*
>
> *Carer 3*

Finally, seven carers mentioned the need for a more holistic multidisciplinary approach to care. Suggestions included therapies aimed at helping male patients, partners and fathers of people with eating disorders, and supporting individuals with comorbidities and issues related to identity.

> *So, you know, by holistic one means not only taking account of comorbidities, if we're going to call them that for the time being, but you know, other parallel problems, whatever it is …*
>
> *Carer 9*

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Brief summary of Study 1

Study 1 was aimed at investigating patients' and carers' experiences of transitioning from hospital care back into the community. Patients' and carers' narratives were analysed through thematic analysis. The themes that were generated highlighted the importance to ensure continued support following hospital discharge and the value of social support, psychoeducation and skill sharing in this difficult phase of recovery.

Study 2: A qualitative investigation of participants' feedback on the ECHOMANTRA intervention

The aim of Study 2 reported in greater detail elsewhere[108] was to collect patients' and carers' feedback on the ECHOMANTRA intervention, including areas for improvement.

Methods

Participants

Participants who had been randomised to the ECHOMANTRA + TAU arm of the trial and had been able to access the ECHOMANTRA intervention resources for a minimum of 6 months were invited to participate. These criteria were necessary to target participants who had had time to familiarise themselves with the content and format of the intervention.

Interview schedule

The interview schedule for the ECHOMANTRA participants included questions about participants' engagement with, and feedback on, the specific intervention components, including online groups, self-help materials (i.e. workbook, videos), as well as the relevance and impact of intervention from their perspective. The same interview schedule was used for both patients and carers. For example, participants were asked, 'Have you booked to attend the online support groups? If so, did you participate or observe?', 'How did you find them [the groups]?', 'What were your thoughts on the materials provided (i.e. workbook, videos)?', 'To what extent was the content applicable to your own personal challenges?', 'What has been your overall experience of participating in this research project?'. For the full interview schedules, see *Appendix 9*.

Data analyses

The data were analysed using thematic analysis, following the same process reported in Study 1.

Results

Participant characteristics

In total, 20 participants were recruited, including 10 patients and 10 carers. The sample included four patient–carer dyads (i.e. cases from the same family). Patients were aged 18–35 (M = 24.10, SD = 4.86), of whom all (100%) were female and of White British ethnicity. Patients were recruited on average 9.5 months following recruitment into the trial (in days, M = 293, SD = 64), from 14 of the 31 TRIANGLE sites, of which 80% were receiving inpatient treatment and 20% were receiving day care. Of the 14 services, eight were NHS and six non-NHS centres, with locations covering London (South East, South West, and North West London); the North West, North East, East, South East, and South West of England; and the Midlands. All patients suffered from AN when they joined the trial and had a low BMI (M = 15.89, SD 1.16) and a duration of illness ranging from 2 to 13 years (M = 6.60 years, SD = 4.03). When not in hospital, six patients (60%) lived with their parents/relatives, two patients (20%) lived with their partners, one patient (10%) lived with friends/flatmates and one patient (10%) lived alone. Carers were aged 48–63 years (M = 53.20, SD = 5.12). Nine out of 10 (90%) were female, and all (100%) were of White British ethnicity. Nine carers were parents of the trial participants with AN, and one was a male partner.

Summary of patients' and carers' experiences of the ECHOMANTRA intervention

Five superordinate themes related to both patients' and carers' experiences of participating in the ECHOMANTRA intervention were identified.

Theme 1: Mixed experiences of the intervention

This theme reflects the thoughts and reflections of those who participated in the ECHOMANTRA intervention. Reports included both valued aspects of the study along with those of a more unhelpful nature. There was considerable appreciation of the positive benefits of identifying and receiving support from others, along with gaining a deeper insight and understanding into their perspectives. There were also reports, however, of some aspects being triggering, tiring and draining.

Impact of identifying and connecting with others

All carers and patients who attended the online groups reported valuing 'a community of people around you that were facing similar things' (Patient 9). This sense of community was based on perceived emotional (e.g. encouragement, validation) and practical support (sharing successful strategies, tips etc.).

> *I feel support from the other carers, you know, if you're having a bad day and you just really struggling, you get a lot of support when everyone else must be feeling exactly the same. It's really good to know that you're not alone.*
>
> *Carer 6*

> *Sometimes it is great to hear other people and when you're in a stronger mind frame sometimes you can offer support or advice or your own reflections.*
>
> *Patient 1*

Of note was that patients and carers who had not actively participated in online groups also expressed feeling a supportive peer community through reading transcripts of past groups or reading comments on the open forums.

> *The fact that people were supporting each other … and when someone asked a question that maybe I would have asked, even though I wasn't there to ask it, it was quite nice to see other people's answers to it.*
>
> *Patient 5*

New insights and perspectives

The online groups, especially those joint with patients and carers, were very highly valued from participants, especially with regard to aspects of novelty ['completely different experience' (Patient 3)] and enhanced understanding into different perspectives.

> *There's aspects that are applicable, things that aren't but they may crop up and you might not realize at the time that they're relevant and then afterwards think 'oh I never thought about that, I never saw it that way' so I think it just helps give a slightly different perspective on things.*
>
> *Carer 4*

> *I particularly found it brilliant that some of the participants were sufferers, eating disorder sufferers and I, and young girls like my daughter so it helped me see their point of view. I found that very helpful.*
>
> *Carer 2*

> *I liked the fact that some of them are joint with the carers because a lot of the time the carers have quite a good perspective to put on it as well, so I think that's quite helpful, even for me hearing the experience of other people's carers and parents, that's quite motivating.*
> *Patient 5*

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Both patients and carers reported finding it easier to hear from people with shared experiences who were not their own family members. Being able to practise speaking about difficult matters and sharing feelings appeared to facilitate more open communication within patient and carer relationships.

> *[other patients] might be saying something that our loved one feels they can't say … and if you hear how somebody else is struggling then maybe in a conversation with [your loved one] in weeks to come, you can kind of ask questions that perhaps you hadn't thought about.*
> *Carer 8*

Acceptability of videos and transcripts

This subtheme reflects participants' experience of listening to videos, reading online groups' transcripts and connecting/identifying/relating to the voices of those focusing on recovery. Patients placed more emphasis on the importance of hearing recovery experiences than carers. It was particularly helpful to hear that aspects of eating disorder recovery were challenging. A patient who did not engage in online groups found the videos a valuable source of recovery inspiration.

> *It's great to have a video saying: 'it's fine if you feel like this at this stage right now and that doesn't mean that you're not actually recovering' or 'it doesn't mean that you're completely relapsing if this happens' … it's that kind of information and normalizing all of these thoughts.*
>
> *Patient 1*

Carers valued the videos as a useful 'snapshot' to boost reflection and as an introductory measure to lead into the forums.

> *… having those little videos just gives you a little snapshot and they're the right length to just get you thinking … they're great ways of leading into the different forums.*
>
> *Carer 4*

Promoting communication

Some participants reported on improved communication between themselves and their loved ones at home, because the online groups had promoted a more adaptive and/or open form of communication and improved relationships.

> *Because we both do it … take part in some of the TRIANGLE project, I think it's brought us closer and has just made us much more open and patient in the way that we communicate and approach each other.*
>
> *Carer 1*

> *After the forum we would have our own discussion about it like you know, I think it worked great.*
>
> *Patient 3*

> *I think so, yeah I think we've been able to be a bit more open with one another, especially after the talks which has maybe made me a bit more open with her.*
>
> *Patient 7*

Some carers reported that the whole structure of the intervention, intentionally designed to involve both patients and carers, supported more collaborative communication.

> *It just gives us a framework for talking ourselves about, about issues.*
>
> *Carer 10*

Others referenced the value of learning specific strategies or models that improved communication, such as the animal metaphors used to represent different caring styles in the New Maudsley Method.

> *I am going a bit more 'terrier' than 'dolphin', though our daughter has called us her 'dolphins' which we found very moving, and we were very pleased that she felt this way.*
>
> *Carer 1*

Challenging aspects of participation

Challenging or unhelpful aspects fell into either structural or personal categories. Structural challenges are listed within the acceptability of remote support theme. Some patients reported that the forums could elicit negative emotions. Some found it draining and sometimes frustrating.

> *… an hour [of group work] is enough. After an hour I think you think 'right,' … it can be a bit draining, you know!*
>
> *Carer 5*

Others reported being triggered by hearing about other patients' experiences of the illness.

> *It was a bit difficult when say someone had gone backwards … because you try and block that out and try and focus on yourself and your own recovery and things like that.*
>
> *Patient 7*

Alternatively, others noted an element of competitiveness.

> *The patient only ones being a little bit competitive and a bit triggering … but to be honest, I've been in a lot of like face-to-face support groups as well and it's always the same. It's always the nature of it.*
>
> *Patient 3*

Theme 2: The need to tailor the intervention to fit stage of recovery

There were many references to the importance of materials and support being tailored to suit both different groups and different stages of change. For example, participants in the study ranged from people who had been struggling with their eating disorder for some time, those who were ambivalent towards the notion of recovery and others moving along the path to complete recovery.

Relevance of resources at different stages

All carers and most patients commented on the value of having the intervention resources available when needed. Particular reference was made to the benefit of this support provided during gaps in treatment or when they were no longer able to access services, such as returning home after discharge from hospital.

> *When I first came out of the hospital, I was using quite a lot of the resources. There was quite a lot going on, so I think it's probably at that time that I used the resources more, when I was sort of struggling a bit more to find my feet again.*
>
> *Patient 9*

Both patients and carers reported referring to the resources as extra support when needed, helpfully supplementing previous work achieved in hospital.

> *I'm finding it more useful at the moment because [the resources] relate to our situation […], it's more poignant I suppose, more helpful … It reiterates what we've learnt when our loved ones were in hospital.*
>
> *Carer 8*

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Many carers made some reference to the wish that they had had access to similar resources earlier when they first began to support their loved ones.

> *If there had been more of this sort of thing early on in her recovery then I really do think that that would have been helpful … I don't necessarily think there's a lot that my daughter can get from this anymore because I think it's all too entrenched.*
>
> *Carer 7*

Motivation and self-efficacy in recovery

Over a half of the participants noted how the ability to benefit from the resources was linked to their own or their supporter's motivation. Equally, engaging with the intervention was also reported to have increased self-efficacy and motivation for continuing recovery.

> *[Engaging with the intervention] kinda made you feel a bit empowered; it gave you 'ooh there's something I can do to help myself in this situation'. It gives you a bit of hope and inspiration.*
>
> *Patient 9*

Carers primarily referenced noticing improvements in their loved one's self-efficacy and motivation in recovery, for example:

> *She is becoming more responsible for her wellbeing.*
>
> *Carer 8*

Carers spoke about becoming less reliant on support as their loved ones' recovery improved.

> *more recently I've not joined them (forums), because we've moved on but that's only because, you know things have got so much better.*
>
> *Carer 2*

Ambivalence towards recovery

Nearly all patients reported challenges engaging with the intervention when experiencing ambivalence about continued recovery post discharge.

> *It's hard for someone with an eating disorder too, when you don't have the motivation to use [the tools], especially if it's self-help. In a self-destruct illness, self-help sometimes isn't … it's good when you're at the stage of motivation to change.*
>
> *Patient 10*

Some patients and carers with a long illness expressed indifference towards their participation, particularly in cases where the illness was more entrenched.

> *I think sometimes if you've been ill for a very long time – I've had this disorder for 13 years and I think it can feel a bit disheartening sometimes because you feel that there's a message that's maybe not for someone like you.*
>
> *Patient 4*

Carers too appeared to show traces of 'illness fatigue' having been through many treatment and psychoeducational programmes.

> *they're fine, useful but at the end of the day, there's nothing really made much difference.*
>
> *Carer 7*

Others acknowledged that their loved ones were still too unwell to fully use the intervention.

> *My daughter's not at the stage where she wants to contribute on the forum, so it's quite interesting to see that she's not quite there yet.*
>
> *Carer 6*

Theme 3: Carer involvement

Subthemes within carer involvement contain reports on both carer strengths and their creativity when it comes to approaching the myriad of different challenges present when living alongside an eating disorder. There are also numerous references to the impact of living alongside an eating disorder on their own emotional and physical well-being.

Carer efficacy

Narratives that demonstrate carer determination, unconditional love and motivation to support their loved ones were evident throughout the interviews. Examples include carers applying skills, techniques, tried and tested strategies as well as recognising the importance of self-care, such as building support networks for themselves and offering support to others.

Nearly all carers reported that participation in the study had improved their understanding of the illness. Online groups were the most frequently referenced resource by carers for developing skills and confidence. In particular, the practical aspects of the group were cited as being valuable.

> *I would use the skills and the things that I had learned to help me … I always challenged myself to take away one or two things that you would actually use.*
>
> *Carer 2*

Furthermore, carers appeared to gain confidence from drawing on others for support and creating boundaries for themselves and in supporting their loved ones.

> *I think it's actually given me the strength to battle some of the battles that we need to […] or going back and having a look at the resources and thinking 'ok yeah now is not the time' and saying things in different ways so actually I feel it's been quite beneficial.*
>
> *Carer 6*

A few patients noticed that their carers had transferred what they had learned into the home environment and that this had had a positive impact on their ability to provide support.

> *they've [online groups] been helpful for my dad … because it just makes him aware … , to manage things and what to say and what not to say, just how to be around the situation.*
>
> *Patient 8*

Toll on carer emotional/physical well-being

There were reports of exhaustion, being overwhelmed, lack of support, challenges with the services or different aspects of service provision, and financial concerns due to having to give up work to care for their loved ones. This acted as a barrier to their ability to collaborate with their loved ones in the intervention.

> *When we joined the trial … I was just exhausted … I wanted to get more involved but part of me that knew emotionally and physically I couldn't do it.*
>
> *Carer 3*

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Some carers reported finding it hardest to use the resources when their loved one was struggling the most, despite acknowledging the long-term benefit this may have had.

> *My daughter's health would dip again and then along with that so would my motivation. … it's the times that you really need the most support that you, you know, that you feel less likely to seek that support.*
>
> *Carer 7*

Theme 4: Acceptability of remote digital support

Participants referred to the challenges that presented themselves while taking part in the study.

Accessible and flexible resources

Many participants appreciated these resources being contained in one space.

> *I think it's nice to have everything in one space, in one area, rather than trawling the internet; I find that very helpful.*
>
> *Carer 8*

The structure was also appreciated by some patients and carers.

> *I think it was quite easy because obviously it takes you right from the very beginning to the very end, so it was quite easy to sort of pick up at the stage you were at.*
>
> *Patient 5*

Others appreciated the flexibility to dip in and out of the workbook, video resources and previous group transcripts, since they were accessible 24/7.

> *I think it's easily accessible like from home, you don't have to go out anywhere but it's just there.*
>
> *Patient 7*

One carer even commented that since the online groups were text-based, this meant it was more possible to join from a variety of locations.

> *… because it's a text feed I used to join them if I was [a passenger] in the car, sometimes I would be on my way home from a parent teacher meeting or something, but I still knew I could log on.*
>
> *Carer 2*

Challenges with online support encountered

Most patients and carers reported challenges with 'glitchy' technology interfering with their use of the resources at some point in their participation, whether due to problems with the website itself, or their own computer or internet connection. Several participants struggled to watch the videos easily on their devices, and others did not like the online groups.

> *I am not very good with sitting behind a computer.*
>
> *Carer 1*

Some participants recommended updating the website and online group formats.

> *maybe making them more friendly for smart phones would be good.*
>
> *Patient 4*

Others commented on problems with the accessibility of groups.

> *The problem with [the groups] they were at certain times when my family would be eating, so it made participation a bit difficult.*
>
> *Patient 6*

One carer reported not having enough time available to engage any resources other than the self-report questionnaires intervention due to her caring commitments.

> *When you're caring for somebody, it's really time consuming and it's draining … I found I didn't have time to do the online forums and the workbooks, but the questionnaires, I knew they would be over in 10 minutes, so I prioritised them.*
>
> *Carer 3*

Others expressed lack of interest in being involved.

> *To be honest I have n't done much with them, I mean I looked through the workbook but yeah I, I don't think I'm there to kind of read through some of that information yet either.*
>
> *Carer 6*

Others noted how the lack of engagement by their carer negatively affected their own engagement.

> *[M]y use [of the groups] has decreased, that's because my mum's use has decreased because she's busier.*
>
> *Patient 3*

Facilitator and moderator guidance

Nearly all participants commented on how the group facilitator and moderators were key to engaging with the online groups.

> *I thought they [the facilitator] were really good because I think they like kind of, they put the direction of what the group needed to go in. There was a start and an end, and I feel that they made people feel like it was a safe place, and everyone was included.*
>
> *Patient 7*

> *I think the facilitator brings it back to be able to discuss you know what was said about the video we'd been watching, and empathetic to how you're feeling but also supportive.*
>
> *Carer 4*

The importance of moderation within the groups was also appreciated.

> *Oh, the moderator is very good, yes, … you need to do that because this is such a desperate time for people that they can get a bit lost in their sadness and their difficulty.*
>
> *Carer 2*

Challenges with joint patient–carer participation

Carers noted challenges in the joint carer forums.

> *I'm worried about what to say on the ones where the patients are there as well … I don't want to say anything to upset anyone.*
>
> *Carer 9*

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Some carers also commented that they found it emotionally challenging.

> *It's much, much harder for me to listen to the patients than the carers because sometimes their circumstances are very difficult, and for people who are not at that stage it's hard to hear what some patients are going through.*
>
> *Carer 5*

Online anonymity

The issue of anonymity within online groups was strongly debated.

> *[anonymity] that's what I thought was quite good about that you didn't have to give a name and a face to it. It was just like 'this is how I feel' and you weren't judged for that.*
>
> *Patient 7*

Whereas some felt that the anonymity reduced their inclination to participate in a group with strangers.

> *There's a kind of anonymity which is great … but it also I find it a bit difficult sometimes to trust or engage with something that's faceless.*
>
> *Patient 1*

Value in helping others

Most patients and carers reported a major incentive for continuing to self-monitor their progress in recovery hoping that documenting and sharing their experiences will help others.

> *There needs to be a dramatic difference in the care that you get in transition and in hospital and when I'm out of hospital, so I think it's just a good thing to have research for and my answers will hopefully have some impact somewhere along the line.*
>
> *Patient 5*

> *I feel like I'm actually kind of doing something positive to help towards eating disorders, in general, so I think for me it's a very personal thing.*
>
> *Carer 6*

Theme 5: The role of self-monitoring and accountability

The narratives in this theme refer specifically to participants' experience of completing the regular self-monitoring forms.

Improved self-awareness

Nearly all participants reported that engaging with the intervention had increased personal awareness about their state of well-being and sense of progress in recovery. Carers reported finding this to be both confronting and constructive.

> *… it actually made me realize how tough I've been finding it. You don't often take time out to think about where your emotions are at … I think the longer you don't acknowledge the difficulties you're facing, the harder it is to be able to support the person you support.*
>
> *Carer 4*

Several patients referred to completing self-report questionnaires as an opportunity to remain aware of their progress after discharge.

> *I think just the check-in, like being forced to check in with myself each month while I was in hospital and then during the transition out – that, it sorts of reminded me like*
> *I notice little habits are different as well. …So, I've really persevered and stopped … myself from going back to certain habits.*
>
> *Patient 8*

Practical and emotional effort

Most participants reported that the emotional effort required to reflect and engage with the intervention resources and questionnaires could also act as a barrier.

> *… having to be honest about how you feel, you know, people may want to avoid that.*
>
> *Carer 5*

Some participants also suggested that it was challenging to make time for activities that involved self-reflection, particularly when busy or when dealing with difficult circumstances.

Pressure for perfection

Some participants commented that they had avoided engaging with the resources due to shame about progress in recovery.

> *Sometimes if you know something has been particularly bad, you might not want to touch on something so negative, you know, so you do try and hide how you're coping because you feel a bit of a failure if you're struggling …*
>
> *Carer 6*

And some patients even acknowledged feeling guilty about lack of progress to report to the study team.

> *Sometimes I really do feel that I'm having a moment where I haven't made enough progress, I haven't done what I should have done or there's no movement. I think it is a personal pressure.*
>
> *Patient 1*

Brief summary of Study 2

Study 2 was aimed at examining patients' and carers' experiences of participating in the ECHOMANTRA intervention and using the online groups and videos. Patients' and carers' narratives were analysed through thematic analysis. The themes generated highlighted both strengths and weaknesses of the online intervention. Strengths included the opportunity to understand both patients' and carers' perspectives during the joint online groups, and the flexibility ensured by the technology. Limitations of ECHOMANTRA related to both personal and technical aspects. Personal issues included burden and exhaustion due to the illness impacting on motivation and time availability to participate. Technical issues included difficulties with using and relying on technology to participate.

Study 3: Quantitative feedback on engagement with, and acceptability of, the ECHOMANTRA intervention, including obstacles to engagement

The aim of this quantitative process evaluation was to obtain a more representative indication of engagement with, and acceptability of, the intervention and its components.

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Method

Participants

All participants randomised to the ECHOMANTRA arm of the trial were invited to complete feedback forms at the end of the study.

Measures

The measures included: (1) data recorded by the study platform regarding participation in the online groups and (2) self-report feedback forms.

Engagement with online group forums

Participation in an online group was recorded through the group transcripts automatically saved on the TRIANGLE website. To be counted, participants had to have posted in the chat box at least once during the group, so that their PIN number could be recorded in the transcript. The number of groups attended per participant were manually counted by a research assistant using these transcript records. Data on participants who joined the online group but did not post any message and data on those who downloaded the transcripts were not captured by the platform.

Intervention feedback form

Participants were asked to complete the 'Intervention Feedback Form' between 12- and 18-month follow-up. The feedback form was developed by the research team and included multiple-choice questions to assess self-reported engagement with, and experience of, the intervention components (i.e. features of the online groups, video library, workbooks). Each item was rated on a five-point Likert scale from 1 to 5, except when participants were asked to name their most useful component of the intervention. For example, 'What proportion of the video clips did you manage to watch?' [from 1 ('none or very few') to 5 ('all or almost all')]. For the full feedback forms, see *Appendix 10*.

Obstacles to engagement feedback form between 12- and 18-month follow-up.

Participants who had not engaged or engaged very little in the intervention were invited to complete the obstacles to engagement feedback form. The obstacles to engagement feedback form were developed by the research team and included overarching questions with subitems to assess obstacles to engagement. For example, the question 'What were the main obstacles for you to engage with the TRIANGLE study?' included statements such as 'Lack of time due to commitments related to treatment'. and 'The content (i.e. topics covered in the workbook, videos, forums) was not appealing …'. Each statement was rated on a Likert scale from 1 ('never an obstacle') to 7 ('always an obstacle'). The questionnaire also included three free-text items, for example, 'Were there any other features (not listed above) that impacted your ability to engage with the materials? Please explain briefly'. For all items, see *Appendix 10*.

Data analyses

Descriptive statistics were produced for the quantitative data (i.e. group attendance, and quantitative ratings within the feedback forms) using IBM SPSS Statistics version 27 (IBM Corporation, Armonk, NY, USA). The free-text data from the obstacles to engagement feedback form from patient and carer participants were analysed together using thematic content analysis by one research assistant (DCB). Thematic content analysis seeks to identify, analyse and report patterns and themes in qualitative data (Braun and Clarke, 2016). The approach to the coding process was primarily deductive given that coding was informed by existing theory and responses provided within structured questionnaires. However, codes were conceptualised flexibly into meaningful units, subthemes and themes as required to reflect the broader discourse. The aim was to provide a systematic description of both the manifest and latent content of the data, and in the end to evolve new concepts and understanding of phenomena (Braun and Clarke, 2016). Data analysis was undertaken concurrently with data collection using NVivo for Mac version 1.0.

Results

Participant characteristics

Demographic and clinical characteristics of all participants in the ECHOMANTRA arm of the trial can be found in *Chapter 3*.

Engagement with facilitated and moderated online group forums

Adherence to this component of the intervention was defined as both the patient and carer attending at least four of the online group sessions. Only 19.46% patient–carer dyads adhered to this criterion, thus a large proportion of non-adherence was observed. A larger proportion of patients (*n* = 82, 44%) and carers (*n* = 82, 44%) had participated in a minimum of one group (for the full breakdown of frequency data for patients and carers, see *Report Supplementary Material 1*, *Tables 7* and *8*).

Intervention feedback form

A total of 74 patients and 60 carers completed the main intervention feedback form on average at 15.8 months post randomisation (SD = 4.13; median = 17.5, IQR = 12.0–19.0). *Table 37* describes participants' ratings of engagement, feasibility and acceptability of the ECHOMANTRA intervention components.

TABLE 37 Participants' ratings of engagement, feasibility and acceptability of the ECHOMANTRA intervention components

	Patients = 74 *N* (%) or Med (IQR)	Carers = 60 *N* (%) or Med (IQR)
Engagement		
What proportion of the workbook did you manage to read?		
None or very little	30 (40.5%)	20 (33.3%)
A quarter to half	25 (33.8%)	24 (40.0%)
All or almost all	19 (25.7%)	16 (26.7%)
What proportion of the video clips did you manage to watch?		
None or very little	27 (36.5%)	16 (26.7%)
A quarter to half	33 (44.6%)	30 (50.0%)
All or almost all	14 (18.9%)	14 (23.3%)
Feasibility		
How easy it was for you to view the video clips?	3.00 (3–4)	3.0 (3–4)
How easy was it for you to use the online groups?	3.00 (2–4)	3.0 (3–4)
How well did the facilitator guide the groups?	5.00 (4–5)	5.0 (4–5)
Acceptability		
How useful did you find the information in the video clips?	3.00 (2–4)	3.00 (3–4)
How useful did you find the information in the workbook?	3.00 (2–3)	3.00 (3–4)
How useful did you find the joint group sessions?	3.00 (2–4)	3.00 (2–4)
How useful did you find the comments made by other individuals?	3.00 (2–4)	3.00 (3–4)
How understanding was the facilitator of the groups?	5.00 (4–5)	5.00 (4–5)
How much did you look forward to attending the groups?	3.00 (2–4)	3.00 (2–4)

Note
Ratings on a five-point Likert scale from 0 to 5 (higher number indicates more positive).

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Obstacles to engagement feedback form

Thirty-five patients and 14 carers completed the obstacles to engagement feedback. *Table 38* shows the extent to which participants experienced obstacles to engagement with ECHOMANTRA. When the answers to open questions were analysed, four major themes were identified as obstacles to engagement, including challenging content/avoidant strategies, level of commitment, lack of individualisation, and the remote, anonymous design. These themes, along with subthemes, are summarised in *Figure 17*.

TABLE 38 Participant self-report ratings of obstacles to engagement with the ECHOMANTRA intervention

Obstacles to engagement	Patients = 35 Med (IQR)	Supporters = 14 Med (IQR)
Lack of time due to treatment commitments	4.00 (3–5)	–
Lack of time due to caring for the patient participant	–	4.00 (3–5)
Lack of time due to other caring responsibilities	2.00 (1–4)	4.00 (3–5)
Lack of time due to child care difficulties	1.00 (1–1)	1.00 (1–2)
Lack of time due to work or study commitments	4.00 (3–5)	4.00 (1–5)
Intervention content not appealing	4.00 (2–5)	3.00 (1–4)
Intervention format not appealing	4.00 (2–4)	2.00 (2–3)
Access problems	1.00 (1–4)	2.00 (1–4)

Note
Each statement was rated on a Likert scale from 1 ('never an obstacle') to 7 ('always an obstacle').

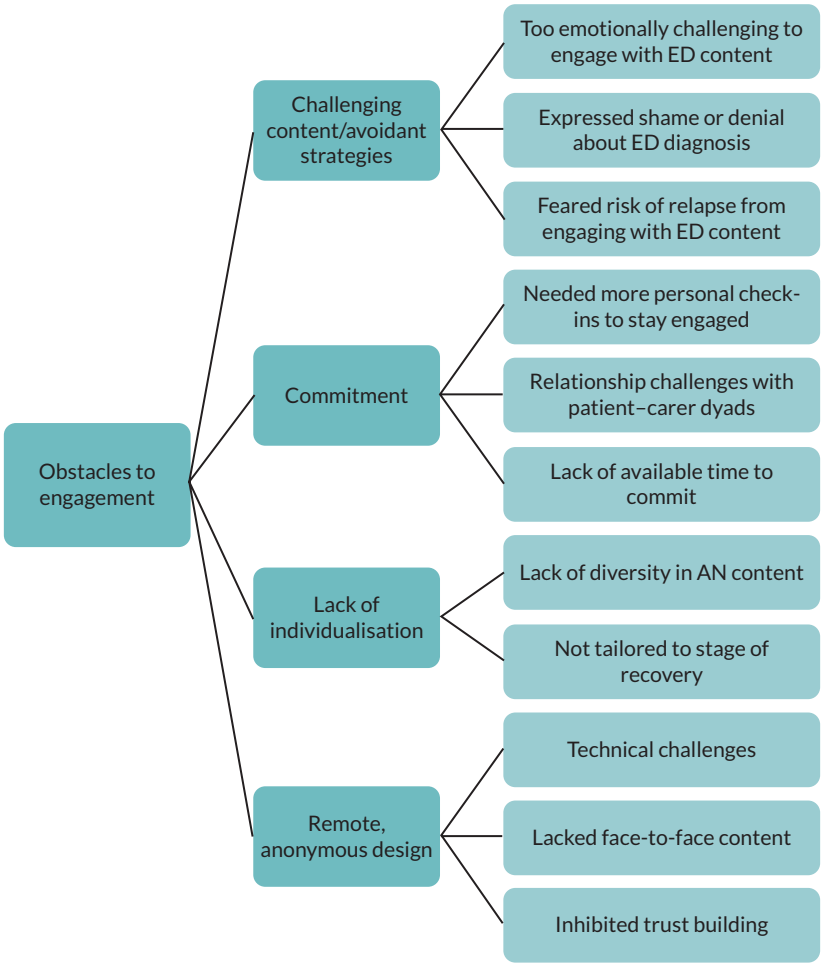

FIGURE 17 Thematic map of obstacles encountered with engagement in the ECHOMANTRA intervention, informed by the perspective of patients (n = 35) and supporters (n = 14) who attended fewer than four of the facilitated and moderated online groups. ED, Eating disorder.

Brief summary of Study 3

Study 3 was aimed at examining adherence to the ECHOMANTRA intervention and obstacles to engagement. Adherence with the intervention was suboptimal with just under 20% of the patient–carer dyads reaching the criterion to establish adherence. The feedback obtained highlighted time constraints and limited appeal of the intervention contents and/or format for some participants.

General discussion

The themes identified in Study 1 provided some insights into factors that can help to facilitate a successful transition from hospital to home and some of the challenges faced by both patients and carers following discharge. While one overarching theme was the acknowledgement of heightened ambivalence during transition, patients and carers also placed considerable value on planning for continuity of care and the need for both expert and social support at this time, including peer support (opportunities to connect with other patients and carers). There was also a consensus that the transition period poses unique challenges and that more tailored solutions considering diversity were needed. For example, offering more personalised plans that could address issues surrounding identity (e.g. gender, sexuality) and comorbidities (e.g. autism) together with the eating disorder could be of value. An important theme that emerged was that many carers were accessing support from a variety of sources (for further discussion of these findings, see Clark *et al.*[13]).

The themes identified in Study 2 on the whole provided support for the acceptability and utility of the ECHOMANTRA intervention, though some negative aspects were reported by both patients and carers. In line with the feedback from Study 1, the overarching theme 'experiential perspective of participation' highlights the considerable value that both patient and carer participants placed on the opportunities to connect with peers, most notably through the facilitated and moderated online groups. Another key theme 'tailoring the intervention to stage of recovery' highlights the importance that both patients and carers placed on the suitability of the materials and timing of receiving those for people at different stages of treatment and stages of illness/recovery journey. The theme of 'carer involvement' highlights the improved understanding of the illness and ability to provide support as described by carers and noticed by patients. The theme 'acceptability of remote support' highlights that participants valued the accessible and flexible nature of the intervention and appreciated the collection of resources in one place on the website. They also appreciated the role of the facilitator and moderator during the online groups. However, mixed preferences about face-to-face delivery versus remote support, together with the technical challenges that can act as obstacles to engagement, suggests that a more flexible approach to delivering resources and support might be needed.

The feedback obtained in Study 3 provided additional insight into the wider engagement with the intervention and the feasibility and acceptability of the intervention delivery and its components. The findings of low participation in the facilitated and moderated online groups and low self-reported use of the workbook and video library suggested that participant engagement was a key problem for both patients and carers. Concurrently, patients and carers on average rated the intervention components as easy to use and online group facilitation as high quality. Therefore, issues related to feasibility of use are unlikely to have been pervasive obstacles to engagement in the study for most participants. Similarly, the usefulness ratings for the content of the workbook, video clips and online group sessions were positive on average, and the facilitator's sense of understanding was rated highly. Thus, it is unlikely that the problem of engagement was heavily influenced by the acceptability of the intervention delivery or its contents.

Multiple factors affected participants' ability to engage with the intervention. External factors, including lack of time due to treatment-related commitments and work/study commitments, and difficulties identifying with the content and the format of delivery, were rated as equally influential to patients' lack of engagement. Similarly, carers acknowledged lack of time due to caring for their loved ones, other caring responsibilities, and work/study commitments as equally detrimental to their engagement in the study. The themes identified from the free-text responses provide further details about the obstacles encountered by participants and areas for improvement. For instance, the theme 'challenging content/avoidant strategies' highlighted that, for some participants, a major obstacle was avoidance of eating-disorder-related content in general due to its potential emotional impact at that time. Offering additional support to manage this

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could be one way to increase engagement. The themes 'commitment', 'lack of individualisation' and 'remote, anonymous design' together highlighted limitations of the intervention. For example, monitoring progress might be used to increase support for those with dips in motivation. An increased consideration of diversity might increase engagement of those with different presentations of the illness, and those at different stages. Incorporating personal interactions and face-to-face contact time might also increase engagement.

Conclusion

This chapter highlights some of the challenges and possible solutions for providing transition care. Taken together, the findings from the three studies validate the need for improved support during the transition from hospital to home. All three studies highlight the need for continued monitoring of progress. The feedback from studies 2 and 3 on the whole supports the acceptability of the materials but note that the lack of personalisation reduced engagement. Thus, a web platform or app with resources might serve a role as the backdrop to transition care offering resources that could be delivered by people with lived experience or in the early stage of their careers. However, more guidance and integration from other components of the service which could tailor aftercare for the diversity of motivation, length of illness and comorbidity might be needed. This process evaluation highlights the advantages of using a mixed-methods approach to understand the factors influencing engagement with the intervention and to identify possible solutions informed by participant feedback.

Chapter 6 Overall discussion and conclusions

The TRIANGLE trial set out to explore the clinical effectiveness and cost-effectiveness of ECHOMANTRA at 12 months post randomisation as a form of augmentation to transition treatment following a period of inpatient or day patient treatment for AN. This was a pragmatic trial undertaken in both the NHS and independent care settings and was representative of the range of commissioned services for this patient group across the UK. The process evaluations undertaken with trial participants added insights into the experiences of participants about future developments.

Key findings

The trial sample was representative of a population of adult AN patient and their carers admitted for inpatient/day patient treatment in the specialised facilities across the UK. We evaluated outcomes at 12 months post randomisation. The offer of ECHOMANTRA treatment did not impact on patient or carer outcomes. It is important to note that these analyses reflect group outcomes and may hide variability within the populations.

Principal outcomes

Both trial arms appeared to show a decrease in our primary outcome, distress (DASS) at 12 months, over the course of the trial (*Chapter 3*, *Figure 7*) but with no statistically significant difference between the study arms.

Secondary eating disorder outcomes

Over time, most outcome variables improved, although most patients remained symptomatic. However, motivation for change was reduced and self-rated ability to change remained low at 12 months. At 12 months, the level of bed use was reduced. Again, there was no statistically significant difference between the study arms.

Economic analysis

The economic analysis found that there was also no overall difference in all health service utilisation, as well as in productivity losses and out-of-pocket expenses. There were no significant differences in quality of life, as measured by the EQ-5D, although quality-of-life gains were greater for TAU. ECHOMANTRA was therefore dominated by TAU as the former had both higher costs and lower levels of quality-of-life gain.

Potential confounding factors

There are several reasons that might explain the finding that ECHOMANTRA had no impact on the outcome at 12 months. These include (a) the low level of adherence to the intervention, (b) changes in quality standards related to carer involvement applied to inpatient treatment and (c) the wider dissemination of support for carers.

Adherence to the intervention

Based on the limited participant-level data regarding the use of the ECHOMANTRA materials, it appears that the overall uptake of the offer was poor. For example, most of the dyads did not take up the full intervention when allocated to the ECHOMANTRA arm. Only 20% of participants actively contributed to the group support component of the ECHOMANTRA intervention. Interestingly, there was wide variation in the uptake (e.g. one patient and carer attended over 50 groups). Sensitivity analysis conducted as part of the economic analysis suggested that participants who did engage in four or more group online sessions had significantly higher levels of quality of life, lower productivity losses and less out-of-pocket expenses than ECHOMANTRA participants who did not engage with the intervention sufficiently. Healthcare costs were also lower, although the difference was not significant. This might suggest that a useful area for further evaluation is to look at ways of improving intervention engagement, as highlighted in a further report detailing the lessons learned from the study.[109]

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Unfortunately, the platform did not register individual engagement with the additional written and video materials of the intervention. In those who provided feedback, the level of engagement with these materials reached 60–70%.

The quality standards required from inpatient services (Quality Network for Eating Disorders, Care Quality Commission, Royal College of Psychiatrists)

A minimal set of quality standards, monitored on biannual inspections, have been developed for inpatient eating disorder services.[81] There is very little in the QED standards that relates to aftercare. There is only a type 3 standard that reads 'Teams provide specific transition support to patients when their care is being transferred to another unit, to a community mental health team, or back to the care of their GP'.[81] Out of the 13 service reviews with data from 2022, only 4 (31%) met this standard.[81]

However, also of relevance to ECHOMANTRA, in the latest edition, services are required to signpost carers to sources of support. These have been refined over time.

In the first edition (2013), there was no specific standard relating to carer involvement other than the following statement: 'The principal carer is contacted during the patient's admission and offered a meeting with a named professional, during which:

- the carer's views about ongoing and future involvement are recorded
- the carer is given an explanation and information sheet about ward/unit procedures etc
- the carer is offered information on carer advocacy
- staff explain how carers can contact the ward/unit for extra information, advice or support as needed, including outside of planned meetings'.

In the second edition (2017), a specific section on carer information (2.10.7) has been added. This states that

> *The team provides each family/carer with a carer's information pack which includes the names and contact details of key staff members on the unit. It also includes other local sources of advice and support such as local carers' groups, carers' workshops and relevant charities.*[110]
>
> *p. 19*

In the third edition (2021), the section on carer information (5.2.5) was updated to:

> *The team provides each carer with carer's information. Information is provided verbally and in writing (e.g., carer's pack). This includes the names and contact details of key staff members on the unit and who to contact in an emergency. It also includes other local sources of advice and support such as local carers' groups, carers' workshops and relevant charities.*[81]
>
> *p.17*

The feedback we obtained in Study 1 about aftercare suggested that carers in this arm accessed various forms of information, including access to support groups both within the service and more generally. This would have minimised the difference between the arms of the intervention.

Changes in the availability of carer skills training and information

Several charities now provide information and support for carers. For example, some of the components of the carer intervention (ECHO) are now available through charities such as Beat, the Charlie Waller Foundation, Bodywhys and FEAST. Additionally, a published manual[76] describes carer support for adults. This would minimise differences in the treatment environment for carers between groups and may have contributed to the failure to find a difference between the two arms of the study.

Ambivalence

A key theme running through the consideration of the results of this trial is the issue of ambivalence about the need for help, a core aspect of AN. This feature may have contributed to engagement with the study protocol and the ECHOMANTRA intervention.

Adherence to the study protocol

The levels of adherence to the study protocol in terms of providing follow-up data were poor with some small differences between groups. For example, in the early phase (3 months), the level of engagement between groups was similar [76% (142/185)] engagement in the ECHOMANTRA group and 73% (136/186) in the TAU group. However, attrition increased at later time points, particularly from the ECHOMANTRA arm of the study. For example, ECHOMANTRA participation in the trial at 12 months was 59% (110/185), whereas TAU participation at 12 months was 77% (143/186), and at 18 months ECHOMANTRA was 53% (98/184) and TAU participation was 66% (123/186). However, the methods of analysis (MI) were designed to reduce any missing data biases.

Compliance with inpatient treatment

Over 20% of the participants had experienced their inpatient care under the aegis of the MHA. For all patients, self-ratings of motivation and ability to change were low at baseline.

Participant feedback

The process evaluation used a mixed-methods approach to obtain participant feedback in order to consider how to optimise transition support for people stepping down from inpatient/day patient care (Study 1) and to understand the factors influencing engagement with the ECHOMANTRA.

Feedback about the current management of transition from inpatient services

Ambivalence about the need to change was cited as a major impediment to recovery identified by patients, although they recognised that both social and service support could mitigate this obstacle. Carers' feedback was also that the transition pathway needed to be individualised and mapped onto the stage and form of illness.

Feedback about the ECHOMANTRA intervention

The qualitative feedback from participants in the ECHOMANTRA arm of the study echoed that from people in the TAU arm in that there was an emphasis on tailoring transition support to the stage of illness and the level of ambivalence about recovery. Although the range of materials on the website was welcomed, it was suggested that improved signposting to aid navigation was needed.

Carers particularly valued connection and support from others, but the fatigue and burden associated with the illness interfered with engagement. For example, for some, the groups often clashed with mealtimes, which are often protracted.

Approximately, a third of patients and carers gave process feedback. The utility of the group support and the form of facilitation was highly rated by attendees. Approximately, a third of patient and carers had minimal engagement with the workbook and videos. For the most part, lack of time was the main reason for non-engagement, but others cited obstacles, including the remote, anonymous design with a lack of individualisation and consideration of diversity.

How does this study compare with the literature?

This is the largest randomised controlled study that has examined interventions to support aftercare in AN. This study was preceded by the CASIS study (n = 178)[6,73] and the iMANTRA study (n = 41).[65] There were similarities and differences in the design of these studies which were all set within specialised eating disorder services within the UK and examined forms of aftercare.

The CASIS study (an intervention for carers) found differences in carer well-being and service use between the group randomised to the ECHO intervention and those given TAU.[6,73] Several possible explanations may account for this difference in the findings between TRIANGLE and CASIS. First, more than one carer per family was invited to participate in the CASIS study, whereas in TRIANGLE only one carer was invited. The cognitive interpersonal model postulates that inter-reactions within the family can serve to maintain the illness. Thus, by focusing on one patient–supporter dyad, we may have inadvertently contributed to the fragmentation within the family which our research has shown has a negative effect on outcome.[44] This may have contributed to the failure to find that ECHOMANTRA improved outcomes. Another difference between the two trials was that the CASIS study included a younger cohort of patients, with a shorter duration of illness (6.2 years) than that in TRIANGLE (8.1 years). There is

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increasing evidence that early interventions, within 3 years of onset (such as used in the FREED study), are associated with a better outcome.[3,111] Also, approximately 20% of TRIANGLE participants had mandatory treatment where there is a requirement to hold Section II7 discharge meeting to plan aftercare. Nevertheless, this group, in general, have poorer outcomes.

The iMANTRA study involved a form of guided self-help to augment aftercare and was more individualised than that provided in TRIANGLE, but even so therapists noted that it was difficult to develop an alliance and suggested that more connection with the inpatient staff would have been of benefit.

Patient and public involvement

One of the strengths of the study was the high level of PPI involvement in all aspects of stages of design, delivery and dissemination of TRIANGLE. In the following summary, we outline PPI involvement using the guidance for reporting involvement of patients and the public 2 framework.

Patient and public involvement in the background design and aims of the study

Patient and public involvement with feedback and interaction in the design of all elements of the study evolved over time and formed the background rationale and design of the materials. This took many forms, and started with carers' conferences, with a focus on contributions from people with lived experience as patients and carers, which were held biannually at the South London and Maudsley Hospital from 1995. People with lived experience were on the steering committee and gave presentations at these conferences. These provided the inspiration for the development of the New Maudsley Method of Collaborative Care, the principles of which were encapsulated in a book coedited and written with people with lived experience.[112] There is now a second edition of the book.[75]

We have followed the procedure of developing complex interventions outlined by the Medical Research Council.[113] Throughout this process, people with lived experience have worked with our research team as academics, clinicians or volunteer advisors developing and testing the materials. This has ensured that the study materials/format/procedures/language used met the needs of both the patient and carer populations. However, the diversity within the PPI group was limited and possibly biased towards those with higher education.

The design and testing of the carer intervention started with small proof-of-concept studies[114,115] investigating treatments targeting aspects of the cognitive interpersonal model.[48] For the TRIANGLE study, people with lived experience, including current patients (n = 3), those in recovery (n = 4) and carers (n = 5), were involved in various roles as research partners and helped to identify and refine the original research questions.

Patient and public involvement in the methods

Developing the ECHO (carer) part of the intervention

People with lived experience (n = 3) were involved in working with the professional team designing and delivering the ECHO intervention in the early developmental studies as facilitators.[116] In later studies, we trained and supervised carers to provide peer support as individual mentors (n = 7).[6,117] The delivery and supervision team reflected on the content and process of ECHO and guided the direction of the future form content. For planning the TRIANGLE study, we consulted with the advisory body of expert mentors (patients and carers) from our previous studies. These mentors gave feedback from their experience of supporting carers and patients with the self-management materials in the CASIS[6] and SHARED trials.[68] Additionally, a patient with lived experience set up the charity SUCCEED and worked with us to develop a set of videos which demonstrated carer skills. A carer took the lead writing the manual on how to deliver the carer skills workshops[76] and created a website with videos and short toolkits. Charities such as Beat, Bodywhys and First Steps have adapted our skill-sharing methods.[118] More recently, we have worked with another carer-led charity, Family Mental Wealth, to develop videos for families to raise awareness of the broader range of eating disorders.[119] Finally, a carer with lived experience and a doctoral degree centred on the CASIS study[6,73,120] is a co-applicant on TRIANGLE and has led the qualitative aspects, run many family workshop training in Scotland and virtually across the world, and written a book describing carer skills.[121]

Developing the RecoveryMANTRA (patient) part of the intervention

The intervention materials were codeveloped with people with lived experience by recording recovered patients' authentic, unscripted stories and conversations about their recovery experiences, challenges and lessons learned. These were framed within the theme 'the things I know now which I wish I knew then'. Three people with lived experience applied to the centre for voluntary research experience and worked with student volunteers to design, edit and evaluate these within an interactive cycle of pilot testing. The recovery MANTRA materials were used as a form of outpatient augmentation in the SHARED study, and a subgroup of the mentors delivering this intervention had lived experience.[68]

Transition care in anorexia nervosa through guidance online from peer and carer expertise design, process and management

A representative from Beat, the largest UK eating disorder charity, and a carer were co-applicants on the grant and contributed to the design, training and study process. The lived experience NIHR reviewer suggested depression, anxiety and stress as the primary outcome, and this change was adopted into the study design.

The majority of the research assistants and facilitators of the online groups employed on TRIANGLE had lived experience and led the PPI advisory team contributing to the ground rules for the group forums and the procedures for moderation. The solution-focused approach to facilitation (using a motivational interviewing communication style) and moderation of the group discussion was piloted with a small group of patients (n = 3) and carers (n = 3) who provided feedback before the groups were launched with the study participants.

One patient with lived experience and one carer with lived experience were to serve on the trial management committee throughout TRIANGLE and contributed regularly to the written materials such as the surveys, monthly newsletter and other correspondence with the trial participants. They contributed to key decision-making during the progress of the trial. For example, the TRIANGLE team consulted the committee on issues such as recruitment methods, COVID-19 and key changes to the study protocol (e.g. changing the format of the joint dyad sessions, which were originally to be delivered via videoconferencing, to multidyad sessions delivered using an online text-based group format).

Patient and public involvement in the results: contributions to study outcomes and impact

We undertook process and qualitative feedback studies led by lived experience members of the team. This included the experience of the transition period in general[13] and specifically relating to the experience of the ECHOMANTRA intervention (detailed comments are given in *Chapter 5*). There was large variation in the attendance of the groups, and only a fifth of participants attained the pre-set minimal dose. Participants explained that competing demands on their time made attendance difficult. Interestingly, some noted reading the group transcripts. Those who gave feedback were positive about the intervention, particularly the group facilitators and the mixed patient/carer groups. However, several people recommended that the intervention would benefit from being more tailored and personalised.

Patient and public involvement in reflections and critical perspectives: contributions to the discussion, conclusions and impact of the study

The early results were presented and discussed at a QED conference (July 2022) and at the annual conference at the Royal College of Psychiatrists (November 2022), both of which had good representation of people with lived experience. The carer representative on QED provided feedback on a preliminary version of this report as well as on a revised version with feedback from reviewers. Feedback from all these sources suggested that a focus on diversity would be of value. Further dissemination is ongoing. Carers with lived experience have continued to train and deliver on the carer materials. Training from a mixed lived experience and professional team on the MANTRA materials funded by the Health Education England (HEE) started in 2021–7.

Participant representation: equality, diversity and inclusion

Participants were recruited from clinical sites within England and Scotland (there are no inpatient services for adults in Wales or Northern Ireland). We included NHS-commissioned services within both independent and NHS facilities. The broad spread of recruitment sites, with different organisational infrastructure, made it difficult to get accurate estimates

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of the processes involved in recruitment such as the overall number of patients initially considered for eligibility. Thus, there is some uncertainty whether recruitment is fully representative of patients within these services or whether the recruitment process posed barriers to some ethnic groups. In the protocol, we excluded those with more complex treatment needs such as people with comorbid health conditions (i.e. type 1 diabetes and cystic fibrosis). Unfortunately, the sociodemographic questions relating to gender and sex did not encompass the diversity which is now recognised to be of relevance for this patient group.

Equality, diversity and inclusion

Although the population recruited into TRIANGLE was somewhat limited in terms of racial, ethnic diversity, and their sexual and gender diversity was not asked about, on the whole they are representative of people undergoing inpatient care as part of treatment for their AN in the UK. However, there was a wide development age of the participants, and it is possible that in some cases the materials did not match participant needs.

In order to explore the issue of diversity after recruitment to TRIANGLE closed, we conducted a supplementary, evidence-based co-design project (EBCD) in order to review the self-care tools and consider representation of issues such as gender, sexuality and ethnicity (unpublished manuscript). Four 90-minute online workshops involving 36 people co-facilitated by three PPI leads, academic researchers and clinicians explored two key research questions: 'How do you see yourself reflected in our existing tools?' and 'How can we make these tools more relevant?'. The workshops were transcribed, and thematic analysis was used to analyse the data. Full details of the EBCD project are provided in *Report Supplementary Material 1*.

Our intervention was designed to offer support to carers as well as patients. We used a broad definition of 'carer' to include any nominated support person, such as a partner or roommate, rather than restricting our intervention solely to those in a strict caregiving role. We are mindful that our strategy of recruiting patient–carer pairs into the study may be less easy or acceptable in cultures in which there is ambivalence about the concept of mental health which may mean that carers may be less willing to participate. We have had conversations about this possible barrier with patients and team members with more knowledge about this context. Although our research assistants did not detect this as a barrier to inclusion, it does not rule out the possibility that the nature of the intervention itself may have limited participation from those with diverse cultural backgrounds. Unfortunately, we did not collect data on factors such as religion, country of birth and family origins, because these are known to be sensitive issues. This limits our ability to draw conclusions about our sample representativeness in these domains. The delivery of our intervention, therefore, occurred within a relatively limited cultural context.

It is possible that socioeconomic factors may have limited the diversity in our sample. For example, the timings of the online groups may not have accommodated different employment circumstances. Also, Wi-Fi access may have been a limiting factor. For example, at some clinical sites we engaged in active troubleshooting (e.g. providing Wi-Fi access) to facilitate participation.

Feedback from the EBCD consultation process (unpublished manuscript) has led us to consider various strategies to recruit from a more diverse population by using inclusive artwork and ensuring that the language on information sheets is acceptable and understandable to all groups. Also, the materials and recovery stories might benefit from the inclusion of more cultural signs associated with various forms of diversity. For example, we could ensure that the recovery narratives feature individuals across different stages of recovery as well as those representing different racial, ethnic, gender, socioeconomic backgrounds and varied geographical regions within the UK. Because our intervention was offered only in English, that may have prevented access among non-English-speaking migrant populations or those with English as a second language.

TABLE 39 Application of the NASSS framework to evaluate ECHOMANTRA

NASSS domain	Application	Description
The condition	Severe, complex AN	Patient: complex aetiology and maintenance factors, high risk and ambivalent about change, high relapse, comorbidity, poor prognosis. Carers: exhausted, hopeless, anxious/distressed, may have a range of reactions that contribute to family fragmentation and illness maintenance.
The technology	Online resources and text-based group support	Psychoeducational materials and recovery-oriented, inspirational videos for patients and supporters, accompanied by online text-based group support for patients, carers and joint groups for both. Group support was implemented in lieu of individual support for feasibility and fiscal reasons. This may have compromised personalisation/reduced appeal for some individuals. Further attention towards representation of more diverse narratives may enhance personal connection and thereby utility of tools.
The value proposition	High cost and high risk of relapse	Provide a low-cost, scalable online intervention to support aftercare and reduce risk of relapse. Broader range of tools and more interactive tasks may facilitate accountability and engagement. Physical monitoring is a weak link in aftercare: in TRIANGLE, 52% had episode of weight loss over 1 kg in a month. Better progress mapping may aid in early detection of relapse cues and provision of 'just in time' intensive work. Participant feedback about monitoring was positive. Linking this with a personalised interaction may be of benefit.
The adopters	Provide guidance and support for patients and carers	Patients were asked to not disclose trial arm to treating clinicians to maintain blindedness, but this may have adversely impacted engagement and reduced integration with usual care. The limitation of support to one carer may have produced the unforeseen consequence of fragmenting support. Engaging broader support networks may help develop a recovery identity.
The organisation	Inpatient and day patient specialist services for eating disorders throughout the UK (independent and NHS)	Variability in services, potential difficulties in integrating NHS and independent systems. Potential failure to reach certain populations, particularly under-represented individuals and cultural groups.
The wider sociopolitical context	Changes in commissioning services	Shifts in commissioning services may provide better aftercare (e.g. more effective and flexible step-down aftercare).
The evolution of each domain over time	Adapting materials and integration across services	We plan to adapt the toolkit and supplementary materials for more diverse populations following on from our EBCD work package. For example, these materials are being adapted for other age groups, languages, and for use in individual and group settings. There has been a great deal of progress examining the needs of patients in the early stage of the illness, for example, within child and adolescent services and the FREED service for adults, but there has been less research and service development of patients with a severe long-standing disorder and for those with other minority subpopulations. It would also be possible to embed TRIANGLE tools into new aftercare services.

Strengths

To the best of our knowledge, TRIANGLE is the largest RCT to have been undertaken worldwide in the treatment of eating disorders. The large number of patient and carer participants recruited supports the feasibility of recruiting patients with severe forms of AN and their carers for similar trials in the future.

Limitations

One limitation is that detailed information about participants' TAU was not systematically collected (e.g. which types of therapies they each received). Given that TAU was not determined by the study team, there was inevitably some variation in the therapy modalities received by study participants across the treatment centres involved. Another

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limitation is that we had originally intended to make use of routine hospital episode statistics in England to also inform the economic analysis and potentially reduce levels of missing data on use of hospital-based care. We relied solely on self-report using an adapted version of the CSRI; while this instrument is widely used with good levels of recall on use of healthcare and other services, the severity of AN might hamper data collection.

Another limitation was that there was a considerable amount of missing data. One can never be sure that there are no unobserved variables driving missingness (i.e. missing not at random missing data generating mechanism). However, considerable efforts were made to identify observable drivers of missingness and used them in a MI approach.

A minor limitation is that the measures used in the study were chosen based on those validated in adult samples. Therefore, these measures may have been less reliable for participants aged 16 or 17 years.

Similarly, while insufficient knowledge of English was an exclusion criterion for the study, the reading and concentration levels of some participants may have also impacted on the take-up of the intervention and completion of the questionnaires. While these variables were not directly assessed within the sample, it is possible that these problems affected some participants given the known effects of AN on cognitive functioning.

Furthermore, these findings may not generalise to other healthcare systems, as TRIANGLE was conducted mainly within the NHS (England), where treatment provision is free at the point of use (including the independent hospitals commissioned to provide care). Therefore, it is difficult to generalise to other systems of care. There are some minor differences in the commissioning models of the devolved nations (Scotland, Wales and Northern Ireland). This study was conducted at a time when most inpatient and day patient services were centrally funded, whereas funding for adult community services was locally funded. The economic analysis also has limitations given that data on resource utilisation, costs and quality of life were collected at two time points, baseline and 12-month follow-up. A further data collection, for instance, at 3-month or 6-month follow-up, may have revealed further impacts on both quality of life and resource utilisation, including the risk of relapse, that we have not been able to account for. The trial had also planned to make use of Hospital Episode Statistics to obtain data on inpatient care, but the data obtained from NHS Digital were of poor data quality and thus were not used. These may have changed the conclusions of the economic analysis. Future economic analyses might also consider impacts on carers, including carer quality of life and carer health service utilisation. Caring for people living with mental health conditions has been shown to have substantial economic value but can also have a detrimental impact on their quality of life, as well as loneliness.[122]

The implications for further development

We used Greenhalgh's Non-Adoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) framework to review and to evaluate the TRIANGLE study[123,124] (*Table 39*) and to consider what has been learned and what might be included to improve aftercare interventions.

Clinical implications: recommendations for aftercare

The following recommendations for patients follow from the synthesis of the findings from the TRIANGLE study.

Core needs

- High levels of communication between patients, carers and primary and secondary levels of care.
- A range of levels of support from social rehabilitation delivered by people with lived experience, through to specialist, intensive interventions.
- The integration between services and task sharing with carers needs to be adapted to the level of risk and treatment targets.
- The type or 'dosage' of the intervention should be adjusted depending on the individual's response as used in adaptive trial designs.[125]

Possible solutions

- A recent meta-analysis showed that individual guidance enhances adherence for online mental health interventions.[126] Thus, a more individualised, guided approach to transition treatment which matches the intensity and form of support with the stage of change might overcome problems caused by ambivalence and mitigate triggering, challenging and unappealing aspects of treatment.
- The joint commissioning for inpatient and outpatient service might enable a form of step-down, integrated service which can build on the in-depth alliance formed during intensive services. The workforce to support this community integration might be early career clinicians (in particular, those people with lived experience).
- The ability to step up to more precise forms of aftercare according to prognostic factors such as length of illness (as in FREED) and comorbidity (such as the PEACE pathway for autism and new treatment pathways for those comorbid with diabetes) and for diversity (gender, sexuality and ethnicity) or possibly by defining individual networks to core targets for treatment have potential.[127]

Recommendations for transition support for carers

Although carers valued the support obtained from connecting with others, the obstacles to engagement with ECHOMANTRA were a lack of time and clashes with other commitments. The provision of a web platform or app for carers with a variety of resources matching the diversity within the patient group and within the forms of available social support may therefore provide a useful and accessible resource.

Currently, charities are providing a large amount of support for carers. Close liaison with clinical centres is needed to ensure regular updating of the evidence. The HEE training course for outpatient teams is closely integrated with people with lived experience and could be used to facilitate this education more widely.

Conclusion

Inpatient care can remediate some of the maintaining factors associated with AN; however, sustaining this change is difficult, and relapse is common. Aftercare is a critical change point and should be the focus of future efforts. With the change in commissioning of services, there is an opportunity to develop a more robust aftercare pathway.

Resources for carers

Carer Support UK – this did not exist in 2015, although their data in 2022 showed that there are over 3400 families registered with them.

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Data-sharing statement

The trial protocol, full study report, anonymised participant level data set and statistical code for generating the results will be made available to other researchers after the publication of the primary outcomes paper, upon reasonable request made to the corresponding author, to achieve aims of an ethically approved proposal.

Ethics statement

This research formed part of the process evaluation of the TRIANGLE intervention registered with ISRCTN: 14644379, on 8 December 2016. The qualitative components are reported in line with the Standards for Reporting Qualitative Research guidance.

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Disclosure of interests

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Primary conflicts of interest: Janet Treasure receives royalties for several books that she has coauthored based on the cognitive interpersonal maintenance model of AN. These include *Skills-based Learning for Caring for a Loved One with an Eating Disorder: The New Maudsley Method* by Janet Treasure, Gráinne Smith and Anna Crane,[128] *Skills-based caring for a loved one with an eating disorder: The New Maudsley Method* by Janet Treasure, Gráinne Smith and Anna Crane,[75] *Caring for a loved one with an eating disorder: The New Maudsley Skills-Based Training Manual* by Jenny Langley, Janet Treasure and Gillian Todd,[76] and *A Cognitive-Interpersonal Therapy Workbook for Anorexia Nervosa for People with Anorexia Nervosa* by Ulrike Schmidt, Helen Startup and Janet Treasure[85] and *Eating Disorders* by Elizabeth McNaught, Janet Treasure and Nick Pollard.[129] Dr Pamela Macdonald also receives royalties for *The Clinician's Guide to Collaborative Caring in Eating Disorders* by Treasure, Janet, Ulrike Schmidt and Pam Macdonald[130] and payments for facilitating carers' workshops based on the New Maudsley Model.

Publication

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Appendix 1 Record of all study amendments

TABLE 40 Record of all study amendments

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
	Change to intervention delivery Joint individual patient and carer guidance sessions replaced with eight online moderated and facilitated group sessions for patients and carers Change to measures Patient *Difficulties in Emotion Regulation Scale*, Carer *Parents vs. Anorexia Nervosa* and *Accommodation and Enabling Scale for Eating Disorders* questionnaires were removed to reduce participant burden			
Substantial amendment 1	Change to inclusion criteria - Patients should either be admitted for inpatient care or should be attending day care for a minimum of 4 days/week at the time of consenting (previously unspecified how long patients should be attending day care for) - Patients previously only included if they suffered from AN, criteria changed to include atypical AN - Clarification that patients must be able to access an electronic device and the internet to log onto the study platform - Informed consent should be provided within 2 months from admission (changed from 1 month) Addition of sites - North Essex Partnership NHS Foundation Trust - Cardiff and Vale University Health Board (NHS) - 2gether NHS Foundation Trust Addition of study documents - Eligibility criteria check list for local investigators and CSO - Pre- and post-discharge clinical team survey - Mentor's questionnaires	1	2 (Protocol 2, 9 February 2017)	7 March 2017
Non-substantial amendment 1	Addition of sites Berkshire Healthcare NHS Foundation Trust South West London and St George's Mental Health NHS Trust	NA	NA	3 May 2017
Non-substantial amendment 2	Addition of sites - Surrey and Borders Partnership NHS Foundation Trust	NA	NA	31 May 2017

continued

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TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Substantial Amendment 2	Change to study documents - Address of participant added to consent forms for reimbursement by cheque - Question added to the consent form asking whether participants are happy to be contacted about other research projects in the future - Patient information sheet (PIS) typo corrected: header 'Version 3_0902' renamed to 'Version 4, 9 February 2017' Change to measures Monthly surveys to clinicians now include information about SAEs Change to consenting process - To improve data security, changed process of sending consent forms from non-NHS sites to the research team at King's College: consent forms now password protected and attached in a normal e-mail to the research team. Change to participant reimbursement Patients now reimbursed by cheque every 6 months during the study rather than at the end. Addition of new sites - Berkshire Healthcare NHS Foundation Trust - South West London and St George's Mental Health NHS Trust - Surrey and Borders Partnership NHS Foundation Trust.	2	3 (Protocol 3, 7 July 2017)	20 July 2017
Non-substantial amendment 3	Change to measures Social Identity Map exercise added to the TRIANGLE website Change to consenting process Clarification that carers can consent from a distance (by e-mail/post). Postage will be reimbursed by the research team	NA	NA	16 August 2017
Non-substantial amendment 4	Addition of new site - Devon Partnership NHS Trust Change to data collection Due to participant difficulty in completing the *CSRI* and *Social Identity Map*, research assistants will now provide telephone guidance to complete these assessments.	NA	NA	11 October 2017
Substantial Amendment 3	Change to measures - Questions regarding perceived treatment credibility and acceptability added to monthly questionnaire for ongoing evaluation of the intervention - Sites will now send medical records, including blood test results, blood pressure, pulse, temperature and saturation, via encrypted e-mail to the research team at baseline and when the patient is discharged.	3	4 (Protocol 4, 28 September 17)	20 November 2017
Substantial Amendment 4	Change to consent forms Patient and carer consent forms revised to include the above changes Change to study documents A typo in the footer of the Patient Information sheet was rectified. It was a discrepancy between the front-page date and the footer date. Change to measures Addition of other eating disorder related measures for patients willing to provide additional data	4	5 (Protocol 5, 8 November 17)	19 January 2018

TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Substantial Amendment 5	Change to protocol - SAEs defined to specify whether they would be considered 'related', 'unrelated', 'expected' or 'unexpected' to clarify which kind of events will be recorded only and which events will need reporting to the REC - Procedure for dealing with protocol violations added to protocol: protocol violations are recorded by the research assistants with justifications. These are discussed during regular meetings with the statistician, and based on those discussions, the study team consider whether an update to the protocol will be necessary - Following under-recruitment from recruiting sites, TRIANGLE research assistants will now visit the participating sites on a regular basis to assist with recruiting and consenting patients - BMI inclusion criteria now applies at the time the patient is approached (not at consent) - Exclusion criteria specifying that patients not admitted to inpatient/day care for a minimum of 4 days/week applies at the time they begin the study (not at consent) Staff/research team changes - Changes to the Data Monitoring and Ethics Committee (DMEC) membership Dr John Morgan has replaced Prof. Hubert Lacey as the DMC chair. Dr Eric Johnson Sabine has replaced Dr Robert Palmer as psychiatrist - Principal investigator change at Barnet, Enfield and Haringey Mental Health Trust – from Dr Lorna Richards to Minna Raikkonen Change to measures Additional questions added to feedback forms to be completed by patients, carers and mentors receiving ECHOMANTRA following the 3-way joint Skype sessions. Change to study documents - Patient information sheet (PIS) typo corrected: header 'Version 3_0902' renamed to 'Version 4, 9 February 2017' - Minor changes to consent forms following feedback from clinical teams that participants often make mistakes and that making the form clearer could help to reduce delays with consenting - Additional study flyer to help with recruitment Addition of new sites - Berkshire Healthcare NHS Foundation Trust - South West London and St George's Mental Health NHS Trust - Surrey and Borders Partnership NHS Foundation Trust. Clarification of participant reimbursement Clarification that the total reimbursement is £60 for patients and £60 for carers.	5	6 (Protocol 6, 1 February 18)	29 May 2018
Non-substantial amendment 5	Changes to study documents - Typo Eligibility Checklist. Staff/research team changes Principal investigator change at South West London and St George's Mental Health NHS Trust – from John Adlam to Jennifer Walker Study flyer typo	6	7 (Protocol 7, 25 July 2018)	31 July 2018

continued

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TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Non-substantial amendment 6	A typo in the study flyer was rectified. It was a discrepancy between the front-page date and the footer date - Corrected: header 'Version 2_21.05.2018' renamed to 'Version 3, 19 September 2018' Principal investigator change Principal investigator change at Northumberland, Tyne and Wear NHS Foundation Trust – from Dr Mark Willis to Dr Caroline Reynolds Addition of new participating sites.	NA	NA	19 September 2018
Substantial amendment 6	The following new participating sites have agreed to take part in the study: - New Market House Healthcare Ltd (non-NHS site) - Cygnet Hospital Ealing, Cygnet Health Care (non-NHS site) - Cardinal Clinic (non-NHS site) Study checklist changes - Changes in inclusion criteria: informed consent will be signed at any time while the patient is admitted into hospital and up to 4 weeks after discharge - Following feedback from clinicians, age also extended to 16 years old so the team can recruit from adolescent units - Change in exclusion criteria: the patient will need to be admitted into hospital or attending day care for a minimum of 3 days/week when they are consented in the study - Change in recruitment into trial: study team will be involved in all the recruitment stages Addition of electronic consent for carers - Due to consenting process of carers delaying randomisation, carers can now provide consent electronically via the study website. Changes in measures obtained from the clinical team and from patients - The clinical teams will no longer be asked to provide monthly updates from patients. Basic clinical information (e.g. BMI, admission/discharge date) will be collected from the clinical teams only at baseline - A brief monthly update questionnaire will be completed by patients instead Carer/family involvement questions Addition of nine questions related to involvement of family members and carers to be asked to the participating sites This brief questionnaire will be completed twice (i.e. at present and 18 months) Research perception questions Addition of six questions related to research perceptions. These questions will be asked to all our participating sites once Study flyer changes Changes in study flyer for patients to make it clearer Study flyer for carers Addition of study flyer for carers. Patients-carers joint sessions change The content of the joint sessions will be delivered via the study website through an online group format instead of using Skype Advertisement of the study on social media The study will be advertised on social media (e.g. Facebook, Twitter). Recruitment of participants in the community Participants will also be recruited in the community if they meet the inclusion criteria (i.e. admitted to hospital or attending day care for a minimum of 3 days/week at the start of the study)	7	8 (Protocol 8, 19 September 2018)	27 December 2018

TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Non-substantial amendment 7	Addition of new site New site has agreed to take part in the study as a participating site. The new site is: Cambridgeshire and Peterborough NHS Foundation Trust	Version 8 Dated: 19 September 2018	Version 9 Dated: 17 January 2019	18 February 2019
Non-substantial amendment 8	Collection of patient BMI from clinical teams - A member of the clinical team at the hospital will be asked to provide patient's BMI measurement at baseline and every 3 months up to patient's discharge Please note that: (a) BMI is already collected as part of routine care (b) This data will be collected for research purposes (c) There is ethics approval to request this data from the medical notes d) Clinical teams were asked to provide this data monthly from the beginning of the study. As part of Amendment No. 6 and to reduce burden on clinical teams, this was changed to be provided at baseline only. However, the team has found that it is difficult to collect this data from participants (e.g. sometimes not aware of BMI as part of treatment for AN) and thus would like to ask again the clinical teams to provide this data at baseline and every 3 months up to patient's discharge Recruitment extension date: Study funder [i.e. NHRI (National Health Research Institute)] has approved extension of recruitment end date until 31 March 2020 instead of the initially proposed date 31 March 2019 Principal investigator change: Principal investigator change at Tees, Esk and Wear Valley's NHS Trust – from Katie Bell to Helen McLay Typo age inclusion criteria We would like to amend the age specified in the inclusion criteria. The approved inclusion age is 16. This was approved in amendment No.6. There is a mistake in the study protocol. The inclusion criteria age should read 'Patients aged 16 years or over' instead of 'Patients aged 17 years or over' Addition of gift vouchers to the reimbursement of participants We would like to offer to participants the option of gift voucher reimbursement as an alternative to the current cheque reimbursement	Version 9 Dated: 17 January 2019	Version 10 Dated: 26 April 2019 Atypical	28 June 2019
Non-substantial amendment 9	Principal investigator changes: Tees, Esk and Wear Valley's NHS Trust – from Helen McLay to Nicholas Wolstenholme NHS Grampian from Jane Morris to Louise Johnston	-	-	23 October 2019
Non-substantial amendment 10	Extension to recruitment end date From 31 March 2020 to 31 May 2020 Change to statisticians listed in the protocol From statistician Emily Robinson to Rachel Holland and health economist from Jennifer Beecham to Eva Bonin	Version 10, dated 26 April 19	Version 11, dated 30 October 2019	18 November 2019

continued

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TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Substantial amendment 7	Additional qualitative data collection - To obtain participant feedback on their participation in the TRIANGLE trial and to gather further information regarding patients' views on transition from intensive treatment, we will: - invite a selected subgroup of patients and carers (up to *n* = 22 patients and *n* = 22 carers, selected based on pre-specified criteria) who were randomised to the ECHOMANTRA + TAU intervention group to participate in an interview about their experience of the TRIANGLE trial and intervention. The maximum number of participants is based on the high likelihood of reaching data saturation on the topic investigated, among the study population, with < 22 participants - invite a selected subgroup of patients and carers (up to *n* = 22 patients and *n* = 22 carers, selected based on pre-specified criteria) who were randomised to the TAU-only group to participate in an interview about their experience of transitioning from the intensive treatment (inpatient or day care) they were receiving when initially recruited to the trial back to the community. The maximum number of participants is based on the high likelihood of reaching data saturation on the topic investigated, among the study population, with < 22 participants - Participants will be recruited who are between the 6-month and 12-month time points in their study participation so that they have had enough time to offer a well-formed opinion of what it meant to them to have participated in the study and to have transitioned from intensive treatment. To explore a range of opinions, participants will be recruited purposively across study sites according to recruitment site location, gender, age, patient's eating disorder severity (> 7 years of illness or below 3 years of illness) and carer's relationship to the patient. Sites will not be involved in the selection of participants. A King's College London researcher, one of the project's coinvestigators, will contact the participants to see if they are willing to take part in the additional interview. Interviews via Skype voice call or by telephone. The interview will last for up to 1 hour and will consist in a pre-specified list of questions. Data will be typed up, allocated an ID number for confidentiality purposes and then analysed - An additional 3 process questions added to the participant feedback form, to be asked to participants in the intervention group at 6 and 12 months in the study	Version 11, dated 30 October 2019	Version 12, 28 January 2020	9 March 2020
Substantial amendment 8	Changes to recruitment procedure due to COVID-19 pandemic During the COVID-19 period, TRIANGLE sites remaining open to recruitment will become Patient Identification Centres (PICs). Local research staff will no longer be required to screen patients. Any staff who identify patients interested in TRIANGLE, or if patients hear about the study through flyers on the wards, patients can directly contact the TRIANGLE research assistants, who will screen and consent patients into the trial remotely using telephone/encrypted e-mail	Version 12, dated 28 January 2020	Version 13, dated 27 March 2020	14 April 2020
Substantial amendment 9	Reconsenting of patients for the collection of their Hospital Episode Statistics (HES) data from NHS Digital. Information sheets and consent forms updated relating to HES data collection, due to previous oversight. Our DMC also advised collecting data on impact of COVID-19 on our participant cohort	Version 13, dated 27 March 2020	Version 14, dated 20 May 2020	2 July 2020

TABLE 40 Record of all study amendments (*continued*)

Amendment	Changes	From protocol	To protocol *N*, version	Date effective
Non-substantial amendment 11	Correction of two errors in the protocol regarding the assessment schedule and study extension (31 October 2021–31 August 2022) Correction of typographical errors in study documents The protocol states that the motivational ruler measure was collected at 3, 6, 9, 12 and 18 months; however, it was not intended to be collected at 9 months, and there is no variable in the study database for this measure at 9 months. This was an error in the protocol and has now been corrected. Carer demographics are on the protocol as only collected at baseline; however, it was possible for carers to change during the study (i.e. a carer could withdraw, and a new carer could consent as a replacement). Therefore, carers could provide updated demographics at each monthly time point throughout the trial. However, no carers changed in the trial in the end, so this error does not affect any participant Extension to study duration that will not have any additional resource implications for participating organisations We received approval from the NIHR-HTA for a non-cost extension to the timeline of the grant. The original end date of the grant was 31 October 2021, and the new end date for the grant is 31 August 2022	-	-	2 November 2021
Non-substantial amendment 12	Extension to study duration that will not have any additional resource implications for participating organisations from 31 August 2022 until 30 November 2022			18 October 2022

Note
Amendments were made to the trial protocol (internal document). The original published protocol[74] was published before these amendments were made.

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Appendix 2 Changes to statistical analyses/reporting since sign-off of the statistical analysis plan

There were a small number of SAP analyses that could not be conducted due to relevant data failing to be collected in the MACRO database. We were able to use a superior approach to modelling site effects than originally anticipated, and we did correct one scoring rule post SAP sign-off. Change to the scoring of CASK total scores: prior to SAP sign-off, e-mail communication between the trial team and the trial statistician working with the team at the time confirmed that CASK scores should be scored such that they take the sum of individual items, with each item scaled down from a total of 100 to a total of 10 (total scale scores ranging from 0 to 270). This information, however, was not translated through to the SAP prior to sign-off, with incorrect scoring information signed off in error.

Amended secondary outcome measure: The secondary outcome, 'Number of days that the patient has spent in hospital during the 18 months post randomisation', was unable to be collected due to a reliance on patient records (Hospital Episode Statistics), which were not made available in time for analyses. Instead, this outcome was amended to reflect self-report information (has the patient used any inpatient services within the last 3 months) captured at baseline and 12-month follow-up from the CSRI database form.

No descriptive statistics reported for treatment receipt of three resources: (1) DVDs, (2) psychoeducational vodcasts and (3) recovery vodcasts. Descriptive statistics for these items were unable to be reported due to it not being possible to collect data on individual video usage due to a fault with the TRIANGLE website which prevented the downloading of this information. Database forms therefore remained missing across each of these items.

Site included as a random effect for analyses of primary and secondary outcomes: within primary and secondary analyses, site effects were handled by the inclusion of site-varying random intercepts as opposed to using fixed effects as stated in the SAP. The decision to use random effects was taken before unblinding and was driven by the larger-than-expected number of sites taking part in the study. Due to the large number of sites, random-effects modelling became an option. This approach is theoretically more appealing in that it estimates intervention effects across a population of sites from which the study sites have been sampled.

Sensitivity analysis for change in carers: the SAP states that, as a sensitivity analysis, the impact of change in carer will be explored. No change to carers, however, occurred throughout the duration of the study and so such analyses are not reported here.

Sensitivity analysis for self-reported weight: listed within the SAP was a reanalysis of patient-reported BMI at 12 months considering only patients who self-reported within 1 month of the expected 12-month outcome time point. However, information on DASS-21 dates needed to identify those who fell within this 1-month assessment window was missing across all patients, and this analysis could therefore not be conducted.

Appendix 3 Participant baseline descriptives split by those randomised before and after 11 March 2020

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TABLE 41 Participant baseline descriptives split by those randomised before and after 11 March 2020

Patient variable	Pre 11 March 2020			Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	Overall – *N* (%) *N* = 337	TAU – *N* (%) *N* = 16	ECHOMANTRA – *N* (%) *N* = 17	Overall – *N* (%) *N* = 33
Age						
Mean (SD)	25.3 (8.3)	25.6 (9.3)	25.5 (8.8)	23.8 (9.4)	26.8 (10.2)	25.3 (9.8)
Median (IQR)	23.2 (19.6–27.7)	22.4 (19.7–28.4)	22.7 (19.6–27.7)	21.7 (17.8–25.6)	23.3 (17.8–34.6)	21.9 (17.8–30.6)
Sex						
Male	9 (5.3)	12 (7.2)	21 (6.2)	2 (12.5)	1 (5.9)	3 (9.1)
Female	161 (94.7)	155 (92.8)	316 (93.8)	14 (87.5)	16 (94.1)	30 (90.9)
Ethnicity						
1. Asian	4 (2.4)	1 (0.6)	5 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
2. Black	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
3. White	161 (94.7)	158 (94.6)	319 (94.7)	15 (93.8)	16 (94.1)	31 (93.9)
4. Mixed	3 (1.8)	7 (4.2)	10 (3.0)	1 (6.2)	1 (5.9)	2 (6.1)
Missing	0 (0.0)	1 (0.6)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Highest completed education						
1. No qualifications	3 (1.8)	4 (2.4)	7 (2.1)	2 (12.5)	3 (17.6)	5 (15.2)
2. O Level/GCSE	30 (17.6)	21 (12.6)	51 (15.1)	4 (25.0)	3 (17.6)	7 (21.2)
3. A Level/NVQ	46 (27.1)	63 (37.7)	109 (32.3)	4 (25.0)	4 (23.5)	8 (24.2)
4. Diploma/BTEC	18 (10.6)	22 (13.2)	40 (11.9)	1 (6.2)	1 (5.9)	2 (6.1)
5. University degree	44 (25.9)	43 (25.7)	87 (25.8)	4 (25.0)	4 (23.5)	8 (24.2)
6. Postgraduate degree	22 (12.9)	14 (8.4)	36 (10.7)	1 (6.2)	2 (11.8)	3 (9.1)
7. Other	6 (3.5)	0 (0.0)	6 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Marital status						
1. Married	13 (7.6)	18 (10.8)	31 (9.2)	1 (6.2)	3 (17.6)	4 (12.1)
2. In a relationship and cohabiting	13 (7.6)	15 (9.0)	28 (8.3)	2 (12.5)	0 (0.0)	2 (6.1)
3. In a relationship and not cohabiting	14 (8.2)	8 (4.8)	22 (6.5)	0 (0.0)	3 (17.6)	3 (9.1)

TABLE 41 Participant baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Patient variable	Pre 11 March 2020			Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	Overall – *N* (%) *N* = 337	TAU – *N* (%) *N* = 16	ECHOMANTRA – *N* (%) *N* = 17	Overall – *N* (%) *N* = 33
4. Single	126 (74.1)	122 (73.1)	248 (73.6)	13 (81.2)	11 (64.7)	24 (72.7)
5. Divorced	0 (0.0)	2 (1.2)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
6. Separated	2 (1.2)	2 (1.2)	4 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
7. Widowed	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Patient recruited while ...						
1. Being admitted for inpatient care	129 (75.9)	125 (74.9)	254 (75.4)	14 (87.5)	15 (88.2)	29 (87.9)
2. Attending day care for at least 3 days per week	41 (24.1)	42 (25.1)	83 (24.6)	2 (12.5)	2 (11.8)	4 (12.1)
Number of daughters						
0	159 (93.5)	155 (92.8)	314 (93.2)	15 (93.8)	14 (82.4)	29 (87.9)
1	5 (2.9)	9 (5.4)	14 (4.2)	1 (6.2)	2 (11.8)	3 (9.1)
2	5 (2.9)	2 (1.2)	7 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	1 (5.9)	1 (3.0)
Number of sons						
0	161 (94.7)	156 (93.4)	317 (94.1)	15 (93.8)	13 (76.5)	28 (84.8)
1	6 (3.5)	7 (4.2)	13 (3.9)	0 (0.0)	2 (11.8)	2 (6.1)
2	2 (1.2)	1 (0.6)	3 (0.9)	0 (0.0)	1 (5.9)	1 (3.0)
3	0 (0.0)	2 (1.2)	2 (0.6)	1 (6.2)	0 (0.0)	1 (3.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	1 (5.9)	1 (3.0)
Height (cm) – mean (SD)	165.2 (7.0) [1]	166.2 (7.7)	165.7 (7.4) [1]	168.2 (7.5)	162.4 (6.6)	165.2 (7.5)
Clinician-reported weight at admission (kg) – mean (SD)	40.0 (5.9) [11]	39.9 (6.3) [12]	40.0 (6.1) [23]	41.5 (8.0)	36.1 (5.1) [3]	39.0 (7.2) [3]
Participant-reported weight (kg) – mean (SD)	43.2 (6.3) [5]	43.9 (7.0) [4]	43.5 (6.7) [9]	46.1 (7.7) [1]	43.3 (6.0) [1]	44.6 (6.9) [2]
Lowest weight since eating disorder began (kg) – mean (SD)	36.7 (5.9) [8]	36.8 (6.3) [5]	36.7 (6.1) [13]	38.7 (6.4) [1]	34.9 (3.8)	36.6 (5.4) [1]
Highest weight ever (kg) – mean (SD)	57.4 (11.9) [14]	58.6 (11.6) [16]	57.9 (11.8) [30]	60.6 (13.3) [2]	55.3 (9.4) [2]	57.9 (11.5) [4]
Weight suppression – median (IQR)	12.0 (7.0–17.0) [18]	12.5 (7.8–20.0) [17]	12.0 (7.4–18.0) [35]	15.3 (5.4–19.4) [2]	8.0 (4.0–18.3) [2]	13.5 (5.4–18.3) [4]

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TABLE 41 Participant baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Patient variable	Pre 11 March 2020			Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	Overall – *N* (%) *N* = 337	TAU – *N* (%) *N* = 16	ECHOMANTRA – *N* (%) *N* = 17	Overall – *N* (%) *N* = 33
Years with eating disorder						
Mean (SD)	8.1 (8.5) [4]	8.1 (8.1) [0]	8.1 (8.3) [4]	4.6 (3.8) [0]	10.8 (10.4) [0]	7.8 (8.4) [0]
Median (IQR)	6.0 (3.0–10.0) [4]	5.0 (3.0–10.0) [0]	6.0 (3.0–10.0) [4]	3.0 (2.0–5.0)	6.0 (4.0–14.0)	5.0 (2.0–10.0)
Number of first-degree relatives with autism						
0	159 (93.5)	153 (91.6)	312 (92.6)	14 (87.5)	13 (76.5)	27 (81.8)
1	8 (4.7)	10 (6.0)	18 (5.3)	1 (6.2)	3 (17.6)	4 (12.1)
2	1 (0.6)	1 (0.6)	2 (0.6)	1 (6.2)	0 (0.0)	1 (3.0)
3	0 (0.0)	2 (1.2)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
4	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	1 (5.9)	1 (3.0)
Number of first-degree relatives with an eating disorder						
0	146 (85.9)	149 (89.2)	295 (87.5)	13 (81.2)	15 (88.2)	28 (84.8)
1	19 (11.2)	15 (9.0)	34 (10.1)	3 (18.8)	1 (5.9)	4 (12.1)
2	3 (1.8)	1 (0.6)	4 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
3	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	2 (1.2)	3 (0.9)	0 (0.0)	1 (5.9)	1 (3.0)
Number of second-degree relatives with an eating disorder						
0	137 (80.6)	148 (88.6)	285 (84.6)	14 (87.5)	14 (82.4)	28 (84.8)
1	26 (15.3)	13 (7.8)	39 (11.6)	1 (6.2)	1 (5.9)	2 (6.1)
2	2 (1.2)	4 (2.4)	6 (1.8)	1 (6.2)	0 (0.0)	1 (3.0)
3	3 (1.8)	0 (0.0)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (1.2)	2 (1.2)	4 (1.2)	0 (0.0)	2 (11.8)	2 (6.1)
Number of first-degree relatives with a mental health illness						
0	84 (49.4)	83 (49.7)	167 (49.6)	8 (50.0)	7 (41.2)	15 (45.5)
1	44 (25.9)	49 (29.3)	93 (27.6)	4 (25.0)	3 (17.6)	7 (21.2)
2	27 (15.9)	20 (12.0)	47 (13.9)	3 (18.8)	4 (23.5)	7 (21.2)

TABLE 41 Participant baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Patient variable	Pre 11 March 2020			Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	Overall – *N* (%) *N* = 337	TAU – *N* (%) *N* = 16	ECHOMANTRA – *N* (%) *N* = 17	Overall – *N* (%) *N* = 33
3	9 (5.3)	9 (5.4)	18 (5.3)	1 (6.2)	0 (0.0)	1 (3.0)
4	1 (0.6)	4 (2.4)	5 (1.5)	0 (0.0)	1 (5.9)	1 (3.0)
5	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
6	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
7	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (1.2)	2 (1.2)	4 (1.2)	0 (0.0)	2 (11.8)	2 (6.1)
Ever been diagnosed with depression?						
No	62 (36.5)	64 (38.3)	126 (37.4)	8 (50.0)	4 (23.5)	12 (36.4)
Yes	106 (62.4)	103 (61.7)	209 (62.0)	8 (50.0)	13 (76.5)	21 (63.6)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with anxiety?						
No	66 (38.8)	70 (41.9)	136 (40.4)	9 (56.2)	5 (29.4)	14 (42.4)
Yes	102 (60.0)	97 (58.1)	199 (59.1)	7 (43.8)	12 (70.6)	19 (57.6)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with OCD?						
No	141 (82.9)	136 (81.4)	277 (82.2)	16 (100.0)	15 (88.2)	31 (93.9)
Yes	27 (15.9)	31 (18.6)	58 (17.2)	0 (0.0)	2 (11.8)	2 (6.1)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with ADHD?						
No	166 (97.6)	160 (95.8)	326 (96.7)	16 (100.0)	17 (100.0)	33 (100.0)
Yes	2 (1.2)	7 (4.2)	9 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with ASD?						
No	158 (92.9)	158 (94.6)	316 (93.8)	15 (93.8)	17 (100.0)	32 (97.0)

continued

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TABLE 41 Participant baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Patient variable	Pre 11 March 2020			Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	Overall – *N* (%) *N* = 337	TAU – *N* (%) *N* = 16	ECHOMANTRA – *N* (%) *N* = 17	Overall – *N* (%) *N* = 33
Yes	10 (5.9)	9 (5.4)	19 (5.6)	1 (6.2)	0 (0.0)	1 (3.0)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with panic disorder?						
No	159 (93.5)	154 (92.2)	313 (92.9)	16 (100.0)	16 (94.1)	32 (97.0)
Yes	9 (5.3)	13 (7.8)	22 (6.5)	0 (0.0)	1 (5.9)	1 (3.0)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with a phobia?						
No	153 (90.0)	158 (94.6)	311 (92.3)	15 (93.8)	17 (100.0)	32 (97.0)
Yes	15 (8.8)	9 (5.4)	24 (7.1)	1 (6.2)	0 (0.0)	1 (3.0)
Missing	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ever been diagnosed with any other psychological disorder?						
No	139 (81.8)	143 (85.6)	282 (83.7)	13 (81.2)	14 (82.4)	27 (81.8)
Yes	28 (16.5)	24 (14.4)	52 (15.4)	3 (18.8)	3 (17.6)	6 (18.2)
Missing	3 (1.8)	0 (0.0)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Ever treated under the MHA?						
1. Yes – currently	34 (20.0)	33 (19.8)	67 (19.9)	2 (12.5)	2 (11.8)	4 (12.1)
2. Yes – previously	30 (17.6)	26 (15.6)	56 (16.6)	2 (12.5)	4 (23.5)	6 (18.2)
3. No – never	106 (62.4)	107 (64.1)	213 (63.2)	12 (75.0)	11 (64.7)	23 (69.7)
Missing	0 (0.0)	1 (0.6)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
If treated under the MHA, how many times?						
Median (IQR)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	2.0 (1.0–2.0)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	1.5 (1.0–2.0)
Ever treated under a CTO?	5 (2.9)	5 (3.0)	10 (3.0)	1 (6.2)	1 (5.9)	2 (6.1)
1. Yes – currently	9 (5.3)	6 (3.6)	15 (4.5)	0 (0.0)	0 (0.0)	0 (0.0)
2. Yes – previously	153 (90.0)	154 (92.2)	307 (91.1)	14 (87.5)	16 (94.1)	30 (90.9)
3. No – never	3 (1.8)	2 (1.2)	5 (1.5)	1 (6.2)	0 (0.0)	1 (3.0)
Missing	5 (2.9)	5 (3.0)	10 (3.0)	1 (6.2)	1 (5.9)	2 (6.1)

GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification.

Appendix 4 Patient and carer data split by those randomised before and after 11th March 2020

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TABLE 42 Carer baseline descriptives split by those randomised before and after 11 March 2020

	Pre 11 March 2020		Post 11 March 2020		
Carer variable	**TAU – *N* (%) *N* = 170**	**ECHOMANTRA – *N* (%) *N* = 167**	**TAU – *N* (%) *N* = 170**	**ECHOMANTRA – *N* (%) *N* = 167**	**TAU – *N* (%) *N* = 170**	**ECHOMANTRA – *N* (%) *N* = 167**
Age – mean (SD)	50.4 (12.9) [2]	50.0 (12.8) [2]	50.2 (12.8) [4]	50.1 (10.9) [0]	48.7 (10.3) [0]	49.4 (10.4) [0]
Sex						
Male	49 (28.8)	50 (29.9)	99 (29.4)	6 (37.5)	6 (35.3)	12 (36.4)
Female	121 (71.2)	117 (70.1)	238 (70.6)	10 (62.5)	11 (64.7)	21 (63.6)
The patient is my …						
1. Spouse	13 (7.6)	14 (8.4)	27 (8.0)	1 (6.2)	3 (17.6)	4 (12.1)
2. Partner	14 (8.2)	15 (9.0)	29 (8.6)	2 (12.5)	1 (5.9)	3 (9.1)
3. Child	127 (74.7)	129 (77.2)	256 (76.0)	13 (81.2)	12 (70.6)	25 (75.8)
4. Sibling	9 (5.3)	3 (1.8)	12 (3.6)	0 (0.0)	1 (5.9)	1 (3.0)
5. Parent	0 (0.0)	3 (1.8)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
6. Other relative	2 (1.2)	1 (0.6)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
7. Friend	4 (2.4)	2 (1.2)	6 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
8. Other non-relative	1 (0.6)	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Current employment status						
1. Paid full-time employment	82 (48.2)	73 (43.7)	155 (46.0)	8 (50.0)	9 (52.9)	17 (51.5)
2. Paid part-time employment	40 (23.5)	42 (25.1)	82 (24.3)	3 (18.8)	5 (29.4)	8 (24.2)
3. Unpaid volunteer work	3 (1.8)	1 (0.6)	4 (1.2)	1 (6.2)	0 (0.0)	1 (3.0)
4. Sick leave	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
5. Unemployed	1 (0.6)	4 (2.4)	5 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)
6. Student or pupil	2 (1.2)	4 (2.4)	6 (1.8)	0 (0.0)	0 (0.0)	0 (0.0)
7. Retired	20 (11.8)	19 (11.4)	39 (11.6)	0 (0.0)	1 (5.9)	1 (3.0)
8. House wife or house husband	10 (5.9)	13 (7.8)	23 (6.8)	1 (6.2)	2 (11.8)	3 (9.1)
9. Other	10 (5.9)	9 (5.4)	19 (5.6)	3 (18.8)	0 (0.0)	3 (9.1)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)

TABLE 42 Carer baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Carer variable	Pre 11 March 2020		Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167
Highest completed education						
1. No qualifications	4 (2.4)	3 (1.8)	7 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
2. O Level/GCSE	30 (17.6)	33 (19.8)	63 (18.7)	2 (12.5)	4 (23.5)	6 (18.2)
3. A Level/NVQ	19 (11.2)	21 (12.6)	40 (11.9)	2 (12.5)	2 (11.8)	4 (12.1)
4. Diploma/BTEC	18 (10.6)	31 (18.6)	49 (14.5)	3 (18.8)	2 (11.8)	5 (15.2)
5. University degree	56 (32.9)	51 (30.5)	107 (31.8)	5 (31.2)	4 (23.5)	9 (27.3)
6. Postgraduate degree	36 (21.2)	25 (15.0)	61 (18.1)	3 (18.8)	5 (29.4)	8 (24.2)
7. Other	6 (3.5)	2 (1.2)	8 (2.4)	1 (6.2)	0 (0.0)	1 (3.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
English as a first language						
No	3 (1.8)	6 (3.6)	9 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)
Yes	166 (97.6)	160 (95.8)	326 (96.7)	16 (100.0)	17 (100.0)	33 (100.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Ethnicity						
1. Asian	5 (2.9)	2 (1.2)	7 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
2. Black	2 (1.2)	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
3. White	159 (93.5)	161 (96.4)	320 (95.0)	15 (93.8)	17 (100.0)	32 (97.0)
4. Mixed	2 (1.2)	2 (1.2)	4 (1.2)	0 (0.0)	0 (0.0)	0 (0.0)
5. Other	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	1 (6.2)	0 (0.0)	1 (3.0)
Marital status						
1. Married	108 (63.5)	108 (64.7)	216 (64.1)	11 (68.8)	12 (70.6)	23 (69.7)
2. In a relationship and cohabiting	25 (14.7)	21 (12.6)	46 (13.6)	2 (12.5)	1 (5.9)	3 (9.1)
3. In a relationship and not cohabiting	9 (5.3)	7 (4.2)	16 (4.7)	0 (0.0)	0 (0.0)	0 (0.0)

continued

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TABLE 42 Carer baseline descriptives split by those randomised before and after 11 March 2020 (*continued*)

Carer variable	Pre 11 March 2020		Post 11 March 2020		
	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167	TAU – *N* (%) *N* = 170	ECHOMANTRA – *N* (%) *N* = 167
4. Single	8 (4.7)	5 (3.0)	13 (3.9)	1 (6.2)	1 (5.9)	2 (6.1)
5. Divorced	16 (9.4)	13 (7.8)	29 (8.6)	1 (6.2)	3 (17.6)	4 (12.1)
6. Separated	1 (0.6)	6 (3.6)	7 (2.1)	1 (6.2)	0 (0.0)	1 (3.0)
7. Widowed	2 (1.2)	6 (3.6)	8 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (0.6)	1 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	0 (0.0)
Number of daughters						
0	35 (20.6)	35 (21.0)	70 (20.8)	3 (18.8)	4 (23.5)	7 (21.2)
1	59 (34.7)	62 (37.1)	121 (35.9)	6 (37.5)	9 (52.9)	15 (45.5)
2	57 (33.5)	54 (32.3)	111 (32.9)	6 (37.5)	4 (23.5)	10 (30.3)
3	14 (8.2)	11 (6.6)	25 (7.4)	1 (6.2)	0 (0.0)	1 (3.0)
4	3 (1.8)	4 (2.4)	7 (2.1)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	2 (1.2)	1 (0.6)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
Number of sons						
0	63 (37.1)	80 (47.9)	143 (42.4)	6 (37.5)	5 (29.4)	11 (33.3)
1	77 (45.3)	61 (36.5)	138 (40.9)	4 (25.0)	8 (47.1)	12 (36.4)
2	21 (12.4)	18 (10.8)	39 (11.6)	3 (18.8)	3 (17.6)	6 (18.2)
3	6 (3.5)	5 (3.0)	11 (3.3)	3 (18.8)	0 (0.0)	3 (9.1)
4	0 (0.0)	1 (0.6)	1 (0.3)	0 (0.0)	1 (5.9)	1 (3.0)
Missing	3 (1.8)	2 (1.2)	5 (1.5)	0 (0.0)	0 (0.0)	0 (0.0)

GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification.

TABLE 43 Baseline patient outcome descriptives split by those randomised before and after 11 March 2020

Patient outcome measure at baseline		Recruited pre 11 March 2020			Recruited post 11 March 2020		
		TAU	ECHOMANTRA	Overall	TAU	ECHOMANTRA	Overall
DASS-21	*N*	170	167	337	16	17	33
	Mean (SD)	72.0 (26.7)	68.9 (28.6)	70.4 (27.6)	68.0 (29.7)	66.8 (23.4)	67.4 (26.3)
EDE-Q	*N*	170	167	337	16	17	33
	Mean (SD)	3.9 (1.4)	3.9 (1.4)	3.9 (1.4)	3.6 (1.2)	3.7 (1.2)	3.7 (1.2)
	Median (IQR)	4.5 (3.2–5.0)	4.3 (3.1–4.9)	4.3 (3.1–4.9)	4.0 (2.2–4.6)	4.0 (2.9–4.5)	4.0 (2.8–4.5)
Patient-reported BMI	*N*	164	163	327	15	16	31
	Mean (SD)	15.8 (2.1)	15.8 (2.0)	15.8 (2.0)	16.3 (2.3)	16.6 (2.1)	16.4 (2.2)
WSAS	*N*	169	167	336	16	17	33
	Mean (SD)	24.9 (9.6)	23.3 (9.4)	24.1 (9.5)	25.4 (5.8)	23.6 (6.6)	24.4 (6.2)
	Median (IQR)	26.0 (18.0–32.0)	24.0 (16.0–30.0)	25.0 (17.0–31.0)	26.0 (24.0–29.5)	23.0 (18.0–28.8)	25.0 (20.0–29.0)
Motivation to change	*N*	169	167	336	16	17	33
	Mean (SD)	7.0 (2.8)	7.1 (2.7)	7.1 (2.8)	6.7 (3.2)	7.6 (2.8)	7.2 (2.9)
	Median (IQR)	8.0 (5.0–10.0)	8.0 (5.0–10.0)	8.0 (5.0–10.0)	7.5 (4.5–9.5)	8.0 (8.0–9.0)	8.0 (6.0–9.0)
Ability to change	*N*	169	167	336	16	17	33
	Mean (SD)	3.8 (2.7)	4.1 (2.7)	4.0 (2.7)	4.5 (2.4)	4.6 (2.2)	4.5 (2.3)
	Median (IQR)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	3.0 (2.0–6.0)	4.5 (2.5–6.5)	5.0 (3.0–6.0)	5.0 (3.0–6.0)
SDQ	*N*	169	165	334	16	17	33
Total scale	Mean (SD)	19.7 (6.0)	18.8 (5.7)	19.3 (5.8)	19.2 (7.2)	18.2 (4.4)	18.7 (5.9)
Peer problems subscale		3.3 (2.0)	3.2 (2.0)	3.3 (2.0)	3.8 (2.5)	3.6 (1.7)	3.7 (2.1)
Prosocial subscale		6.5 (2.2)	6.7 (2.2)	6.6 (2.2)	6.2 (2.5)	5.9 (2.2)	6.1 (2.4)
CSRI	*N*	169	167	336	16	17	33
Inpatient hospital days during prior 3 months	Mean (SD)	50.9 (35.7)	52.9 (35.0)	51.9 (35.3)	52.0 (35.7)	51.7 (35.2)	51.8 (34.9)
	Median (IQR)	45.0 (23.0–83.0)	56.0 (28.0–82.0)	52.0 (24.5–82.0)	50.5 (24.5–77.5)	44.0 (28.0–84.0)	50.0 (28.0–81.0)

Note
Shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

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TABLE 44 Baseline carer outcome descriptives split by those randomised before and after 11 March 2020

Carer outcome measure at baseline		Recruited pre 11 March 2020			Recruited post 11 March 2020		
		TAU	**ECHOMANTRA**	**Overall**	**TAU**	**ECHOMANTRA**	**Overall**
DASS-21	***N***	**170**	**167**	**337**	**16**	**17**	**33**
	Mean (SD)	32.4 (24.9)	32.4 (24.2)	32.4 (24.5)	23.8 (23.7)	28.9 (20.2)	26.4 (21.8)
	Median (IQR)	26.0 (14.0–46.0)	26.0 (14.0–44.0)	26.0 (14.0–44.0)	12.0 (8.0–30.0)	26.0 (12.0–40.0)	22.0 (8.0–36.0)
CASK	***N***	**170**	**167**	**337**	**16**	**17**	**33**
	Mean (SD)	155.7 (41.7)	157.0 (40.5)	156.3 (41.0)	164.9 (37.9)	151.2 (37.9)	157.8 (37.9)

Note
Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

TABLE 45 Patient outcome descriptives at 12 months post randomisation split by those randomised before and after 11 March 2020

Patient outcome measure at 12 months		Recruited pre 11 March 2020			Recruited post 11 March 2020		
		TAU	ECHOMANTRA	Overall	TAU	ECHOMANTRA	Overall
DASS-21	*N*	130	97	227	13	13	26
	Mean (SD)	62.5 (29.0)	58.4 (27.7)	60.7 (28.5)	54.0 (33.5)	53.5 (24.9)	53.8 (28.9)
EDE-Q	*N*	126	95	221	14	13	27
	Mean (SD)	3.5 (1.6)	3.4 (1.5)	3.5 (1.5)	3.6 (1.6)	3.1 (0.8)	3.4 (1.3)
	Median (IQR)	3.7 (2.2–4.8)	3.5 (2.2–4.6)	3.6 (2.2–4.7)	3.6 (2.2–5.1)	3.1 (2.7–3.4)	3.3 (2.4–4.3)
Patient-reported BMI	*N*	122	89	211	11	13	24
	Mean (SD)	17.4 (2.8)	16.8 (2.3)	17.2 (2.6)	17.6 (3.2)	17.4 (2.2)	17.5 (2.6)
WSAS	*N*	120	95	215	14	13	27
	Mean (SD)	18.0 (12.2)	19.0 (11.1)	18.4 (11.7)	17.6 (10.3)	13.8 (7.4)	15.8 (9.1)
	Median (IQR)	17.0 (7.5–28.0)	18.0 (9.0–29.0)	17.0 (8.0–28.0)	16.0 (11.0–23.0)	11.0 (8.0–19.0)	15.0 (8.0–22.0)
Motivation to change	*N*	120	95	215	14	13	27
	Mean (SD)	6.8 (2.9)	7.0 (2.6)	6.9 (2.8)	6.9 (3.1)	6.8 (2.9)	6.8 (3.0)
	Median (IQR)	8.0 (4.0–9.5) [50]	7.0 (5.0–10.0)	8.0 (5.0–10.0)	7.5 (4.0–10.0)	8.0 (4.0–8.0)	8.0 (4.0–10.0)
Ability to change	*N*	120	95	215	14	13	27
	Mean (SD)	3.7 (2.8) [50]	3.7 (2.4) [72]	3.7 (2.6)	4.5 (3.0)	5.2 (3.2)	4.8 (3.1)
	Median (IQR)	3.0 (1.5–5.0)	3.0 (2.0–5.0)	3.0 (2.0–5.0)	4.5 (2.0–6.0)	5.0 (3.0–8.0)	5.0 (2.0–8.0)
SDQ	*N*	94	76	170	13	10	23
Total scale	Mean (SD)	15.7 (7.0)	17.2 (7.2)	16.4 (7.1)	17.4 (6.5)	16.9 (6.9)	17.2 (6.5)
Peer problems subscale		2.9 (2.0)	3.0 (2.0)	3.0 (2.0)	3.2 (2.0)	3.2 (1.9)	3.2 (1.9)
Prosocial subscale		7.0 (2.3)	6.6 (2.0)	6.8 (2.2)	5.9 (2.7)	7.3 (1.8)	6.5 (2.4)
CSRI	*N*	119	95	294	15	12	27
Inpatient hospital days during prior 3 months	Mean (SD)	13.7 (30.0)	13.9 (30.0)	13.8 (29.9)	20.5 (34.7)	23.2 (40.4)	21.7 (36.6)
	Median (IQR)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.0 (0.0–59.0)	0.0 (0.0–49.0)	0.0 (0.0–59.0)

Note
Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

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TABLE 46 Carer outcome descriptives at 12 months post randomisation split by those randomised before and after 11 March 2020

Carer outcome measure at 12 months		Recruited pre 11 March 2020			Recruited post 11 March 2020		
		TAU	ECHOMANTRA	Overall	TAU	ECHOMANTRA	Overall
DASS-21	*N*	**101**	**86**	**187**	**13**	**12**	**25**
	Mean (SD)	29.1 (23.2)	25.4 (18.2)	27.4 (21.1)	33.5 (18.8)	38.8 (18.5)	36.1 (18.5)
	Median (IQR)	24.0 (12.0–38.0)	22.0 (14.0–34.0)	22.0 (12.0–36.0)	28.0 (18.0–44.0)	35.0 (30.0–48.0)	32.0 (24.0–44.0)
CASK	*N*	**95**	**79**	**174**	**13**	**10**	**23**
	Mean (SD)	167.7 (49.4)	155.4 (52.2)	162.1 (50.9)	143.7 (53.9)	144.2 (60.8)	143.9 (55.7)

Appendix 5 Site categories in imputation model

The modelling of the outcome variables required merging the original 31 sites (*Table 7*) into broader site categories to avoid overparameterisation in the imputation model of the MI procedure. Any sites with fewer than five dyads with values on all outcome measures were collapsed with the most geographically close neighbour. This led to the following merged site categories:

- Central and North West London was collapsed with (i) Ellern Mead Centre, (ii) Priory Roehampton, (iii) Ellern Mead Barnet and (iv) Orri ED Clinic
- Cheshire and Wirral was collapsed with (i) South Staffordshire, (ii) Priory Altrincham and (iii) Priory Cheadle
- Avon and Wiltshire was collapsed with (i) Dorset, (ii) Southampton and (iii) Devon
- Cambridgeshire and Peterborough was collapsed with (i) New Market and (ii) North Essex; Northumberland
- Tyne and Wear was collapsed with (i) Tees, Esk and Wear, (ii) Royal Cornhill, (iii) South East Scotland and (iv) Community
- 2gether (South East) was collapsed with (i) Berkshire, (ii) Cardinal Clinic and (iii) Oxford
- Surrey Borders was collapsed with (i) Priory Hayes Grove.

Thus, 11 broad site categories were used in the MI modelling reported in *Tables 14–16* of the main report and also the CCAs (*Appendix 6*, *Tables 48–49*) and the MI modelling (*Appendix 7*, *Tables 50–51*).

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TABLE 47 Baseline variables split by participant missingness of DASS-21 at 12-month follow-up

Baseline variable		Participants with DASS-21 observed at 12 months *N* = 253	Participants with DASS-21 missing at 12 months *N* = 117	Logistic regression *p*-value
N (%)				
Sex	Male	15 (5.9)	9 (7.7)	0.61
	Female	238 (94.1)	108 (92.3)	
Ethnicity (recoded)	0. Non-white	13 (5.1)	6 (5.2)	0.83
	1. White	240 (94.9)	110 (94.8)	
Highest education (recoded)	1. None or other	8 (3.2)	10 (8.6)	0.10
	2. O Level/GCSE	35 (13.8)	23 (19.8)	
	3. A level/NVQ	83 (32.8)	34 (29.3)	
	4. Diploma/BTEC	28 (11.1)	14 (12.1)	
	5. University degree	68 (26.9)	27 (23.3)	
	6. Postgraduate degree	31 (12.3)	8 (6.9)	
Marital status (recoded)	1. Married	25 (9.9)	10 (8.6)	0.45
	2. In a relationship (cohabiting/not)	34 (13.4)	21 (18.1)	
	3. Single, divorced, separated or widowed	194 (76.7)	85 (73.3)	
Ever treated under the MHA followed by a CTO (recoded)?	0. Never	236 (94.0)	101 (89.4)	**0.09**[a]
	1. Yes	15 (6.0)	12 (10.6)	
Patient recruited while …	1. Being admitted for inpatient care	195 (77.1)	88 (75.2)	0.85
	2. Attending day care for at least days/week	58 (22.9)	29 (24.8)	
Ever been diagnosed with depression?	0. No	101 (40.1)	37 (31.9)	0.25
	1. Yes	151 (59.9)	79 (68.1)	
Ever been diagnosed with anxiety?	0. No	109 (43.3)	41 (35.3)	0.24
	1. Yes	143 (56.8)	75 (64.7)	
Ever been diagnosed with OCD?	0. No	212 (84.1)	96 (82.8)	0.84
	1. Yes	40 (15.9)	20 (17.2)	

TABLE 47 Baseline variables split by participant missingness of DASS-21 at 12-month follow-up (*continued*)

Baseline variable		Participants with DASS-21 observed at 12 months *N* = 253	Participants with DASS-21 missing at 12 months *N* = 117	Logistic regression *p*-value
Ever been diagnosed with ADHD?	0. No	246 (97.6)	113 (97.4)	0.89
	1. Yes	6 (2.4)	3 (2.6)	
Ever been diagnosed with ASD?	0. No	237 (94.1)	111 (95.7)	0.50
	1. Yes	15 (6.0)	5 (4.3)	
Ever been diagnosed with panic disorder?	0. No	240 (95.2)	105 (90.5)	0.12
	1. Yes	12 (4.8)	11 (9.5)	
Ever been diagnosed with a phobia?	0. No	237 (94.0)	106 (91.4)	0.21
	1. Yes	15 (6.0)	10 (8.6)	
Mean (SD)				
Age		25.5 (8.6)	25.4 (9.6)	1.00
Number of daughters		0.1 (0.4)	0.1 (0.3)	0.70
Number of sons		0.1 (0.4)	0.1 (0.4)	0.76
N 1st degree relatives with mental health illness (recoded)		1.1 (1.5)	1.0 (1.2)	0.45
Years with eating disorder		8.2 (8.3)	7.8 (8.3)	0.63
Lowest weight since eating disorder diagnosis (kg)		36.7 (6.0)	36.9 (6.0)	0.89
Highest weight ever (kg)		57.6 (11.6)	58.7 (12.0)	0.68
EDE-Q – baseline		3.8 (1.4)	3.9 (1.4)	0.86
Patient-reported BMI – baseline		15.8 (2.0)	16.1 (2.2)	NA[b]
WSAS – baseline		24.2 (9.4)	24.0 (9.0)	0.69
Motivation to change – baseline		7.2 (2.8)	6.9 (2.8)	0.46
Ability to change – baseline		4.1 (2.6)	3.9 (2.7)	0.49
CSRI – inpatient days in hospital during 3 months prior to baseline		49.6 (35.4)	56.8 (34.5)	0.10

GCSE, General Certificate of Secondary Education; NVQ, National Vocational Qualification.
a Significant a $p < 0.1$ and considered a possible predictor of missingness in the primary outcome (DASS-21 at 12 months).
b Model did not converge due to collinearity with existing covariates in available sample.

Note
p-values are based on mixed-effects models with 12-month DASS-21 missingness set as the dependent variable. All models are also adjusted for baseline DASS-21 scores, severity at recruitment (minimisation factor), allocation arm, and also include recruitment site (minimisation factor) as a random effect.

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Appendix 6 Baseline predictors of missing primary outcome

A total of 117 participants (31.6%) were missing DASS-21 data at 12 months [TAU= 43 (23.1%), ECHOMANTRA= 74 (40.2%)]. Baseline predictors of DASS-21 missingness at 12 months were therefore explored to establish whether any necessary adjustments above and beyond the covariates which were pre-planned to be included within the primary outcome model (baseline DASS-21 scores, allocation, and minimisation factors) were necessary to avoid any missing data biases.

Appendix 5, *Table 47* lists the baseline variables which were explored as potential predictors of missingness. Predictors of missingness were investigated by first generating a binary missingness indicator for the primary outcome variable (0 = not missing, 1 = missing) and regressing this on each baseline variable in-turn, together with pre-planned covariates (baseline DASS-21 scores, treatment allocation, and the minimisation factors of illness severity and recruitment site). Specifically, logistic mixed-effects modelling was utilised with recruitment site added as a random effect to account for site effects (N = 31 sites). All other covariates were included as fixed effects.

Baseline categorical variables with low cell counts were collapsed into broader subsets prior to predicting missingness in the primary outcome.

- Ethnicity: 'Asian', 'Black' and 'Mixed' were collapsed into a single 'Non-white' category.
- Highest education: 'No qualification' and 'Other' were collapsed into a single 'None or other' category.
- Marital status: 'In a relationship and cohabiting' and 'In a relationship and not cohabiting' were collapsed into a single 'In a relationship' category, and 'Single', 'Divorced', 'Separated' and 'Widowed' were collapsed into a 'Single' category.
- Mental Health Act: 'Ever treated under the MHA?' and 'Ever treated under a CTO?' were captured by a single 'Ever treated under the MHA followed by a CTO?' variable, with 'Yes – currently' and 'Yes – previously' also collapsed into a single 'Yes' category.
- Relatives with mental illness: counts across 'Number of first-degree relatives with an eating disorder', 'Number of first-degree relatives with autism' and 'Number of first-degree relatives with a mental health illness' were aggregated into a single variable capturing 'Number of first-degree relatives with any mental health illness'.

Baseline variables which were *not* modelled as potential predictors of missingness included the baseline scales of OCI-R and AQ-10 due to both OCD and ASD being captured by the baseline variables 'Ever been diagnosed with OCD?' and 'Ever been diagnosed with ASD?', respectively. Similarly, neither clinician-reported weight nor raw participant weight or height variables at baseline were included due to these variables being captured by the derived 'Patient-reported BMI' variable which was included as a potential predictor.

Any baseline variable with $p < 0.1$ was considered a potential predictor of missingness. In the event that multiple variables were found to predict missingness, a series of forward step-wise logistic models were then planned to find the most important variables associated with missingness in the primary outcome. Following the modelling of each baseline variable in-turn, only one variable – 'Ever treated under the MHA followed by a CTO?' – was found to be associated with 12-month DASS-21 missingness at $p < 0.1$ (see *Appendix 5*, *Table 47*). This MHA/CTO variable was therefore taken forward as an additional predictor of missingness within the primary ITT analysis.

Complete-case analyses of the trial outcomes

A CCA uses the same analysis models as our chosen analysis approach, but instead of imputing missing values simply, analyses of the participants for whom all variables used in the modelling are observed. The approach is less powerful as fewer observations can contribute to the analyses and importantly makes more restrictive assumptions regarding

the variables that are allowed to predict missing values in the respective outcome variable. These are basically the explanatory variables of the analysis model which in our context are trial arm, baseline values of the outcome variable and randomisation stratifiers (site and illness severity).

Tables 48 and *49* show the complete-case estimates for the patient and carer outcomes, respectively. *Table 48* shows that the CCA used information from 253 patients of the 370 dyads randomised in the analysis of the primary outcome, that is, 31.6% were excluded due to missing values. As can be seen from the table, the effect of ECHOMANTRA on the primary outcome of DASS-21 at 12 months was not statistically significant ($p = 0.71$), with 95% CIs spanning the null (95% CI −7.11 to 4.85), indicating that we are unable to reject the null hypothesis of no effect between groups on the primary outcome. *Appendix 6*, *Tables 48* and *49* show that none of the secondary outcomes would have tested statistically significant at the 5% level using this analysis approach.

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TABLE 48 Patient outcomes analyses using complete cases

Patient secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	253	−1.13	(−7.11 to 4.85)	−0.04	(−0.26 to 0.18)	0.71
DASS-21 – 18 months	221	0.57	(−6.44 to 7.57)	0.02	(−0.23 to 0.28)	0.87
EDE-Q – 12 months	248	−0.02	(−0.31 to 0.26)	−0.02	(−0.22 to 0.19)	0.88
EDE-Q – 18 months	206	0.10	(−0.22 to 0.43)	0.08	(−0.16 to 0.32)	0.53
Patient report BMI – 12 months	230	−0.39	(−0.95 to 0.17)	−0.19	(−0.46 to 0.08)	0.17
Patient report BMI – 18 months	200	−0.41	(−1.09 to 0.26)	−0.20	(−0.53 to 0.13)	0.23
WSAS – 12 months	242	1.82	(−0.89 to 4.52)	0.20	(−0.10 to 0.49)	0.19
WSAS – 18 months	206	2.19	(−0.69 to 5.07)	0.24	(−0.07 to 0.55)	0.14
Motivation to change – 12 months	242	0.12	(−0.56 to 0.79)	0.04	(−0.20 to 0.28)	0.74
Motivation ruler: Importance to change – 18 months	205	−0.24	(−0.98 to 0.50)	−0.09	(−0.35 to 0.18)	0.52
Motivational ruler: Ability to change – 12 months	242	−0.17	(−0.79 to 0.46)	−0.06	(−0.30 to 0.17)	0.60
Motivational ruler: Ability to change – 18 months	205	−0.34	(−1.03 to 0.35)	−0.13	(−0.39 to 0.13)	0.34
SDQ total score – 12 months	193	1.20	(−0.29 to 2.69)	0.21	(−0.05 to 0.46)	0.11
	N	**IRR**	**95% CI**	***p*-value**		
CSRI – total length of hospital stay (up to 12 months)	241	0.69	(0.19 to 2.52)	0.57		

IRR, incidence rate ratio.

Note

Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

TABLE 49 Carer secondary outcome analyses using complete cases

Carer secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	212	−1.61	(−6.17 to 2.94)	−0.07	(−0.25 to 0.12)	0.49
DASS-21 – 18 months	183	−2.57	(−7.64 to 2.50)	−0.11	(−0.31 to 0.10)	0.32
CASK – 12 months	197	−9.11	(−21.30 to 3.07)	−0.22	(−0.52 to 0.08)	0.14
CASK – 18 months	173	8.16	(−5.08 to 21.4)	0.20	(−0.12 to 0.53)	0.23

Note

Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

Appendix 7 Multiple imputation analysis of the trial outcomes assuming that non-adherence with ECHOMANTRA does not predict missingness of the outcome variable

We repeated the MI analyses described in the main text but excluded non-adherence with ECHOMANTRA from the imputation model (using 100 imputations). This is paramount to assuming that such treatment non-adherence is not predictive of later missingness of the outcome variable. We conducted these analyses to understand the impact that the various assumptions regarding the missing value generating process had on our findings.

Tables 50 and *51* show the results from these MI analyses for patient and carer outcomes, respectively. *Appendix Table 4* shows that this analysis used available information from all 370 patient–carer dyads. As with CCA, the effect of ECHOMANTRA on the primary outcome of DASS-21 at 12 months was non-statistically significant (p = 1.00), with 95% CIs again spanning the null (95% CI −5.7 to 5.7). *Appendix 7*, *Tables 50* and *51* show that the substantive results of the secondary outcomes are the same as those described in the main text (cf. *Tables 11* and *12*) except for the effects of ECHOMANTRA on WSAS at 18 months not testing statistically significant (cf. *Exploration of work and social adjustment scale scores*).

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TABLE 50 Patient outcomes analyses using MI (no non-adherence adjustment)

Patient secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	370	−0.02	(−5.7 to 5.7)	0.00	(−0.21 to 0.21)	1.00
DASS-21 – 18 months	370	1.03	(−5.40 to 7.47)	0.04	(−0.20 to 0.27)	0.75
EDE-Q – 12 months	370	−0.02	(−0.28 to 0.25)	−0.01	(−0.21 to 0.18)	0.9
EDE-Q – 18 months	370	0.05	(−0.27 to 0.36)	0.03	(−0.20 to 0.26)	0.78
Patient report BMI – 12 months	370	−0.51	(−1.09 to 0.08)	−0.25	(−0.53 to 0.04)	0.09
Patient report BMI – 18 months	370	−0.27	(−0.91 to 0.37)	−0.13	(−0.44 to 0.18)	0.41
WSAS – 12 months	370	1.65	(−1.18 to 4.48)	0.18	(−0.13 to 0.48)	0.25
WSAS – 18 months	370	2.80	(−0.04 to 5.64)	0.30	(0.00 to 0.61)	0.053
Motivation ruler: importance to change – 12 months	370	0.16	(−0.47 to 0.80)	0.06	(−0.17 to 0.29)	0.61
Motivation ruler: importance to change – 18 months	370	−0.07	(−0.77 to 0.64)	−0.02	(−0.28 to 0.23)	0.85
Motivational ruler: ability to change – 12 months	370	−0.07	(−0.67 to 0.54)	−0.02	(−0.25 to 0.20)	0.83
Motivational ruler: ability to change – 18 months	370	−0.23	(−0.90 to 0.44)	−0.09	(−0.34 to 0.16)	0.49
SDQ total score – 12 months	370	1.30	(−0.35 to 2.94)	0.22	(−0.06 to 0.51)	0.12
	N	**IRR**	**95% CI**	***p*-value**		
CSRI – total length of hospital stay (up to 12 months)	370	0.84	(0.30 to 2.37)	0.74		

IRR, incidence rate ratio.

Note

Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

TABLE 51 Carer secondary outcome analyses using MI (no non-adherence adjustment)

Carer secondary outcomes	*N*	Estimated ECHOMANTRA effect	95% CI	Standardised estimate	Standardised 95% CI	*p*-value
DASS-21 – 12 months	370	−1.42	(−5.95 to 3.10)	−0.06	(−0.24 to 0.13)	0.54
DASS-21 – 18 months	370	−2.46	(−7.31 to 2.38)	−0.10	(−0.30 to 0.10)	0.32
CASK – 12 months	370	−11.63	(−24.94 to 1.68)	−0.29	(−0.61 to 0.04)	0.09
CASK – 18 months	370	9.94	(−3.40 to 23.28)	0.24	(−0.08 to 0.57)	0.14

Note

Lightly shaded cells indicate measures, whereby higher scores represent better outcomes (and unshaded the reverse; higher scores represent worse outcomes).

Appendix 8 Interview schedule for Study 1: Experience of transition (*Chapter 5*)

TRIANGLE PROJECT: SEMISTRUCTURED INTERVIEW SCHEDULE (TAU GROUP, PATIENTS)

Interviewer introduces herself and purpose of interview – to explore the experience of the patient with regard to the overall transition process during eating disorder treatment.

We are interested in your point of view. Please tell us openly your experience of transitioning out of intensive treatment.

Specific points to address:

- No right or wrong answers.
- Recording and confidentiality (only for transcribing purposes).
- Transcription – only small, anonymous quotes will be used.
- Length of interview (up to 1 hour).

1. After leaving intensive treatment, what support did you receive?
   Prompt: Residential/day care/outpatient?
2. Any support that was particularly helpful to you or your family?
   Prompt: Medical/nutritional support, peer groups
3. What challenges, if any, did you face upon discharge?
   Prompt: What was unhelpful to you?
4. How did you address these challenges?
   Prompt: What resources were available – support networks and so forth?
5. How difficult or straightforward was it to keep up motivation to continue down the recovery path?
   Prompt: Any specific techniques used?
6. To what extent have your carers been able to support you with the transition process?
   Prompt: Have they needed support? In an ideal world, what support would you like them to have?
7. What suggestions do you have for a seamless transition process?
8. How have you found completing the TRIANGLE questionnaires so far?

Prompt: What personally motivated you to complete the questionnaires? How did you feel after completing the questions?
Any general thoughts regarding your participation in the trial?
Thank you for your time today/this evening. This has been invaluable to us and to research into eating disorders.

TRIANGLE PROJECT: SEMISTRUCTURED INTERVIEW SCHEDULE

(TAU GROUP, CARERS)

Interviewer introduces herself and purpose of interview – to explore the experience of the carer with regard to the overall transition process of their loved one with an eating disorder.

We are interested in your point of view. Please tell us openly your experience of caring for your loved one during the transition process out of intensive treatment.

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Specific points to address:

- No right or wrong answers.
- Recording and confidentiality (only for transcribing purposes).
- Transcription – only small, anonymous quotes will be used.
- Length of interview (up to 1 hour).

1. After leaving intensive treatment, what support did your loved one receive?
   Prompt: Residential/day care/out-patient?
2. After leaving intensive treatment, what support did you receive?
   Prompt: Family therapy? Skills training? Carer groups?
3. Any support that was particularly helpful to you or your family?
   Prompt: Medical/nutritional *support*, *peer groups.*
4. What challenges, if any, did you face upon discharge in supporting your loved one?
   Prompt: What was unhelpful *to you? Helpful?*
5. How did you address these challenges?
   Prompt: What resources *were available – support networks and so forth?*
6. What was your experience with the transition process with regard to your own mental and physical well-being?
   Prompt: How did you take *care of your own needs? How did these fit in with other demands of the caring role?*
7. What suggestions do you have for a seamless transition process?
8. How have you found completing the TRIANGLE questionnaires so far?

   Prompt: What personally motivated you to complete the questionnaires? How did you feel after completing the questions? Any general thoughts regarding your participation in the trial?
   Thank you for your time today/this evening. This has been invaluable to us and to research into eating disorders.

Appendix 9 Interview schedule for study 2: Experiences of ECHOMANTRA (*Chapter 5*)

Interviewer introduction and purpose of interview – to explore the experience of the patient with regard to participation in the TRIANGLE project.

> *We are interested in your point of view. Please tell us openly your ideas and experience of the intervention. We are interested in whether you found the materials helpful or otherwise. We would like your honest opinion, both positive and negative aspects. If, for example, you found them unhelpful or irrelevant please say so, as we want to work on finding the best possible interventions to help you. You are the expert. We want to hear your point of view.*

ONLINE SUPPORT GROUPS

Have you booked to attend the online support groups? If so, did you participate or observe? How did you find them? Prompt: What specific aspects could you relate to?

To what extent did you relate to other group members? Prompt: Did you feel you were there for the same reasons, same goals?

What were your experiences in participating in the joint patient and carer groups in comparison to the patient-only/carer-only groups? Prompt: How did you relate to the carers/patients? How did they relate to you as someone with an eating disorder?

To what extent did you relate to the group facilitator? Prompt: What was their role in making you feel at ease, included, excluded?

To what extent were the groups recovery oriented? Prompt: Can you explain further – in what ways?

What impact did the comments made by others have on you in terms of motivation? Prompt: Change or challenge the eating disorder or no effect/impact?

How did you find incorporating videos into the start of the group?

How did you feel at the end of every online session? Prompt: What aspect of the online group did you attribute this to?

What are some of the pros and cons of online groups? Prompt: Anonymity, facial cues, voice intonation.

MATERIALS

What were your thoughts on the materials provided (workbook, videos)? Prompt: How easy did you find to navigate through them?

What were your views on content? Prompt: Structure, placing. How did they resonate with your own personal needs?

In your opinion, did the components follow a logical pattern? Prompt: How easy was it for you to navigate through the workbooks?

To what extent was the content applicable to your own personal challenges? Prompt: What proportion did you find relevant to your own situation?

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QUESTIONNAIRES AND OVERALL EXPERIENTIAL PERSPECTIVE

How did you find the questionnaires and feedback? Prompt: What personally motivated you to complete the questionnaires? How did you feel after completing the questions?

As you probably know, the questionnaires provide the necessary data to evaluate whether the intervention is a cost-effective service of value for the NHS. What might you think puts people off doing the questionnaires? Prompt: Are there any practical or personal obstacles that make them more difficult to complete?

What do you think might motivate other participants to complete the questionnaires? Prompt: Any other suggestions?

OVERALL

Since you joined the project, what changes, if any, have you noticed to your own well-being?

Was the intervention useful at any particular time in your/your loved one's recovery path? Prompt: Has your use of the resources increased or decreased? Can you describe to us what aspects were useful at what times?

To what extent do you feel the TRIANGLE project has impacted upon any changes, on you or your carer (s)/patient? Prompt: How have these changes impacted on you? What specific aspects of the project do you feel this has been attributed to?

What has been your overall experience of participating in this research project? Prompt: Both positives and negative aspects. What, if anything, did you get out of it?

Thank you for participating in the TRIANGLE project. This has been invaluable to us and to research into eating disorders, in general. Thank you also for your time today/this evening.

Appendix 10 Participant feedback forms

Patient Feedback Form

1.	What proportion of the video clips did you manage to watch?	1	None or very few
		2	
		3	About half
		4	
		5	All or almost all
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
2.	How useful did you find the information in the video clips?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
3.	How easy was it for you to view the video clips (from a practical and technological standpoint)?	1	Very difficult
		2	
		3	Easy
		4	
		5	Very easy
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
4.	What proportion of the workbook did you manage to read?	1	None or very few
		2	
		3	About half
		4	
		5	All or almost all
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

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5.	How useful did you find the information in the workbook?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
6.	How useful did you find the comments made by individuals in the forum?	1	Not at all useful
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
7.	How easy was it for you to use the discussion forum (from a practical and technological standpoint)?	1	Very difficult
		2	
		3	Relatively easy
		4	
		5	Very easy
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
8.	How many joint Skype sessions with your carer and mentor would have been ideal for you? Min = 0 Max = 20		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
9.	How useful did you find the joint Skype sessions?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

10. How would you rate your mentor's skills for the joint sessions with your support person? Joint session: Professionalism	1	Non-professional
	2	
	3	
	4	
	5	Professional
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
11. Joint session: Empathy	1	Not empathetic
	2	
	3	
	4	
	5	Empathetic
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
12. Joint session: Warmth	1	Not warm
	2	
	3	
	4	
	5	Warm and encouraging
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
13. Joint session: Listening	1	Didn't listen
	2	
	3	
	4	
	5	Actively listened
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

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14. Joint session: Understanding	1	Poor understanding
	2	
	3	
	4	
	5	Good understanding
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
15. Joint session: Judgement	1	Judgemental
	2	
	3	
	4	
	5	Non-judgemental
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
16. Joint session: Guidance	1	Too much guidance
	2	
	3	
	4	
	5	Enough guidance
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
17. Joint session: Skills	1	Didn't explain skills
	2	
	3	
	4	
	5	Skills were clearly outlined
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

18. Joint session: Looking forward	1	Didn't look forward to sessions
	2	
	3	
	4	
	5	Looked forward
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
19. How easy did you find to identify a mutually convenient time with your mentor and carer to organise the joint sessions?	1	Very difficult
	2	
	3	Neither easy nor difficult
	4	
	5	Very easy
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
20. What did you find most useful in terms of helping you to develop skills to manage eating disorder and its impact on you and your loved ones: the discussion forum, the workbook, the video clips, or the joint sessions with your mentor and support person?	1	Discussion forums
	2	Video clips
	3	Workbook
	4	Joint sessions with support person and mentor
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

Carer Feedback Form

1. What proportion of the workbook did you manage to read?	1	None or very few
	2	
	3	About half
	4	
	5	All or almost all
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

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2.	How useful did you find the information in the workbook?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
3.	What proportion of the video clips did you manage to watch?	1	None or very few
		2	
		3	About half
		4	
		5	All or almost all
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
4.	How useful did you find the information in the video clips?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
5.	How easy did you find it to view the video clips (from a practical and technological standpoint)?	1	Very difficult
		2	
		3	Relatively easy
		4	
		5	Very easy
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

6.	How useful did you find the comments made by individuals in the forum?	1	Not at all useful
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
7.	How easy was it for you to use the discussion forum (from a practical and technological standpoint)?	1	Very difficult
		2	
		3	Relatively easy
		4	
		5	Very easy
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
8.	How many joint Skype sessions with the TRIANGLE participant would you have been ideal for you? Min = 0 Max = 20		
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
9.	How useful did you find the joint Skype sessions with the TRIANGLE participant?	1	Not at all
		2	
		3	Useful
		4	
		5	Extremely useful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

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10.	How would you rate your mentor's skills for the joint sessions with the TRIANGLE participant? Joint session: Professionalism:	1	Non-professional
		2	
		3	
		4	
		5	Professional
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
11.	Joint session: Empathy:	1	Not empathetic
		2	
		3	
		4	
		5	Empathetic
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
12.	Joint session: Warmth:	1	Cold/cool
		2	
		3	
		4	
		5	Warm and encouraging
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
13.	Joint session: Listening:	1	Poor listener
		2	
		3	
		4	
		5	Actively listened
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

14. Joint session: Understanding:	1	Poor understanding
	2	
	3	
	4	
	5	Good understanding of situation
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
15. Joint session: Judgement:	1	Judgmental
	2	
	3	
	4	
	5	Non-judgmental
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
16. Joint session: Guidance:	1	Not enough guidance
	2	
	3	
	4	
	5	Enough guidance
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*
17. Joint session: Explanation of skills:	1	Didn't explain skills
	2	
	3	
	4	
	5	Skills were clearly outlined
	777	*Not available or not applicable*
	888	*Not done*
	999	*Unknown*

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18.	Joint session: Looking forward:	1	They didn't look forward to the sessions
		2	
		3	
		4	
		5	Looked forward to sessions
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
19.	How easy was it to identify a mutually convenient time with your mentor to organise the joint sessions?	1	Very difficult
		2	
		3	Easy
		4	
		5	Very easy
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
20.	What did you find most useful in terms of helping you to develop skills to manage the impact of the eating disorder on you and your loved one: the forum, the workbook, the video clips or the joint sessions with your mentor?	1	Discussion forum
		2	Workbook
		3	Video clips
		4	Joint Sessions with loved one and peer mentor
		5	*Not available or not applicable*
		777	*Not done*
		888	*Unknown*
		999	*Unknown*

21.	How helpful were the materials (forum, video-clips, sessions) for your own confidence in being able to cope with caring for someone with an eating disorder?	1	Not at all
		2	
		3	Helpful
		4	
		5	Extremely helpful
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
22.	In general, circle the level of practical skills training you think the intervention provides:	1	Too little
		2	
		3	Enough
		4	
		5	Plenty
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*
23.	To what extent did the TRIANGLE study meet your expectations?	1	Not at all
		2	
		3	Met expectations
		4	
		5	Exceeded expectations
		777	*Not available or not applicable*
		888	*Not done*
		999	*Unknown*

Questionnaire for patient non-engagers

1. What were the main obstacles for you to engage with the TRIANGLE study? (i.e. complete questionnaires, use the online resources, attend the forums?)

1.1. Lack of time due to commitments related to treatment

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

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4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.2. Lack of time due to commitments caring for other family members

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.3. Lack of time due to commitments related to child care

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.4. Lack of time due to commitments related to work/study

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.5. The content (i.e. topics covered in the workbook, videos, forums) was not appealing

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.6. The format of the project (i.e. the website, the design/structure of the project) was not appealing

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.7. Problems accessing an electronic device regularly

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.8. Lack of self-motivation

1 = never an obstacle

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2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.9. Lack of accountability for attendance

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.10. Lack of individualised support offered

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.11. Lack of connection/alliance with the group members

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

2. What would you say was the number one reason you felt unable to engage with the TRIANGLE study?

3. Were there any other features (not listed above) that impacted your ability to engage with the materials? Please explain briefly.

4.How could others (e.g. TRIANGLE team, your carers, professionals) have made it easier for you to participate in the project? Please explain briefly.

Questionnaire for carer non-engagers

1. What were the main obstacles for you to engage with the TRIANGLE study? (i.e. complete questionnaires, use the online resources, attend the forums?)

1.1. Lack of time due to commitments related to caregiving for the patient

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.2. Lack of time due to commitments caring for other family members

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

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1.3. Lack of time due to commitments related to child care

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.4. Lack of time due to commitments related to work/study

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.5. The content (i.e. topics covered in the workbook, videos, forums) was not appealing

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.6. The format of the project (i.e. the website, the design/structure of the project) was not appealing

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.7. Problems accessing an electronic device regularly

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.8. Lack of self-motivation

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.9. Lack of accountability for attendance

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

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6 = very frequently an obstacle

7 = always an obstacle

1.10. Lack of individualised support offered

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

1.11. Lack of connection/alliance with the group members

1 = never an obstacle

2 = very rarely an obstacle

3 = rarely an obstacle

4 = occasionally an obstacle

5 = frequently an obstacle

6 = very frequently an obstacle

7 = always an obstacle

2. What would you say was the number one reason you felt unable to engage with the TRIANGLE study?

3. Were there any other features (not listed above) that impacted your ability to engage with the materials? Please explain briefly.

4. How could others (e.g. TRIANGLE team, care team, peer supporters) have made it easier for you to participate in the project? Please explain briefly.

Thank you for taking the time to complete this questionnaire. If you would like to receive £10 reimbursement for your feedback, please enter your e-mail address here:

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HSDR
HTA
PGfAR
PHR

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