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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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Scientific summary

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

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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

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.

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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This article

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