Transition care in Anorexia Nervosa through guidance online from peer and carer expertise (TRIANGLE): Study protocol for a randomized controlled trial.

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Abstract

TRIANGLE is a multicentre trial investigating whether the addition of a novel intervention for patients and carers (ECHOMANTRA) to treatment as usual (TAU) improves outcomes for people with anorexia nervosa (AN). ECHOMANTRA is based on the cognitive interpersonal model of AN and includes assessments, workbooks, videos, online discussion groups and joint Skype sessions for patients and carers. People receiving intensive hospital treatment ($N = 380$) will be randomised to TAU or TAU plus ECHOMANTRA. Participants will be assessed over an 18-month period following randomisation. The primary outcome is patient psychological well-being at 12 months post-randomisation. Secondary outcomes include: a) patient's weight, eating disorder symptoms, motivation to change, quality of life, and number of days in hospital at 12 months post-randomisation; and b) carer's psychological wellbeing, burden and skills at 12 months (some outcomes will also be assessed at 18 months post-randomisation). The results from this trial will establish the effectiveness of ECHOMANTRA.

Transition care in Anorexia Nervosa through guidance online from peer and carer experts

(TRIANGLE): Study protocol for a randomized controlled trial.

Anorexia nervosa (AN) can develop into a severe, enduring psychiatric disorder that is associated with increased mortality rates (Arcelus, Mitchell, Wales, & Nielsen, 2011), substantial physical (Michell & Crow, 2006) and psychological comorbidities and adverse social consequences (Hjern, Lindberg, & Lindblad, 2006). Specialised hospital treatment is recommended for the management of complex and high-risk forms of anorexia nervosa (AN) (NICE, 2004). In the UK, both new and repeat admissions for AN have been increasing since 2000 (Holland, Hall, Yeates, & Goldacre, 2016). Statistics from the National Health Service (NHS) in the UK indicate longer duration of admissions and higher mortality rates post-admission for patients with AN when compared to most psychiatric disorders (Hoang, Goldacre, & James, 2014; Thompson, Shaw, Harrison, & Verne, 2004). According to one estimate, the mean length of stay for specialist inpatient services in Scotland is 113 to 141 days for adults and adolescents, respectively (Morris, Simpson, & Voy, 2015). Research also suggests high rates of hospital readmission for individuals with AN (Steinhausen, Grigoroiu-Serbanescu, Boyadjieva, Neumärker, & Winkler Metzke, 2008) and there is concern about the risk of harm such as from institutionalisation in this patient group (Treasure, Crane, McKnight, Buchanan, & Wolfe, 2011). Therefore, interventions that may optimise the outcome during and following inpatient or day-patient treatment are needed.

According to a recent systematic review, add-on interventions for inpatient care for AN contribute little short-term benefit in terms of weight recovery (Suárez-Pinilla et al., 2015). However, studies examining various forms of aftercare suggest that these programs may be a promising target for further investigation. For instance, post-hospitalisation cognitive behavioural therapy (CBT) demonstrated superiority to nutritional counselling (Pike, Walsh, Vitousek, Wilson, & Bauer, 2003), and educational interventions for patients

(Fichter, Cebulla, Quadflieg, & Naab, 2008; Fichter et al., 2012) and carers (Hibbs et al., 2015a; Magill et al., 2016) have been found to improve outcomes in the adult, more protracted, phase of illness.

Based on the potential of aftercare interventions directed toward patients and carers to improve patient outcomes, and because involving families appears key to strengthening patient social networks and breaking toxic loneliness and isolation (McKnight & Boughton, 2009; Levine, 2012; Treasure et al., 2011), we have developed a skills-sharing intervention for patients with anorexia nervosa and their carers, ECHOMANTRA, to facilitate the transition from hospital back into the community (Table 1). ECHOMANTRA is based on interventions for carers (Experienced Carers Helping Others, ECHO; Treasure, Rhind, Macdonald, & Todd, 2015) and patients (Maudsley Model of Anorexia Nervosa Treatment for Adults, MANTRA; Schmidt, Wade, & Treasure, 2014), developed from the cognitive interpersonal model of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013) (see Table 1). The cognitive interpersonal model of AN highlights the importance of tackling intrapersonal risk factors (e.g., obsessive-compulsive traits and heightened attention to details) and interpersonal relationships to improve patient psychological wellbeing (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013). We will therefore assess patient intrapersonal risk factors, such as obsessive-compulsive traits, to examine whether they moderate treatment outcomes in the current trial. We will also assess patient interpersonal functioning, such as work and social adjustment and autistic-like social difficulties as indicated via self-report and prosocial behaviour and peer problems as indicated via report of carers. Moreover, given the centrality of patient psychological distress (i.e., experiences of depression, anxiety and stress) in AN and the theoretical underpinnings for ECHOMANTRA, we will assess patient psychological distress as the primary outcome in this trial.

Based on the interpersonal model of AN, the "MANTRA" part of the ECHOMANTRA intervention addresses patients' modifiable characteristics, such as difficulties in emotional regulation, interpersonal relationships, and eating. The intervention includes a workbook with an emphasis on specific behavioural change strategies, such as psychoeducation, specific prompts for instruction and practice, explicit tools for encouragement, and a library of short videos of individuals who have recovered and provide behaviour change tips (Cardi et al., 2015a). The intervention focuses on steps to aid thriving after transition by strengthening relationships to family and social groups.

The "ECHO" part of the ECHOMANTRA intervention is directed toward carers and includes three basic components (Treasure et al., 2015). First, ECHO provides carers with information to strengthen coping with the caregiving role. Second, ECHO teaches carers how to reduce emotionally-driven caregiving behaviours, such as high expressed emotion, accommodating and enabling to the eating disorder, as well as disagreement and division within the family. Thirdly, ECHO teaches skills of positive communication and behavioural change in order to support recovery. The ECHO intervention also includes a set of videos and transcripts written and produced by patients and carers showing adaptive and less adaptive support strategies. These videos are linked to a supplementary workbook. Past research suggests that carers' accommodating behaviours are a key maintaining element of the illness (Treasure et al., 2008) and even minor shifts in this behaviour can contribute to clinical change (Salerno et al., 2015). Interestingly, we have found that when carers follow ECHO, social functioning improves in their adolescents with AN (Hibbs et al., 2015a). This suggests that ECHO likely goes beyond increasing practical meal support skills to also indirectly helping with social and emotional functioning.

Given research supporting the utility of moderated and facilitated online discussion forums (Kendal, Kirk, Elvey, Catchpole, & Pryjmachuk, 2016) and therapeutic chat groups

(Zerwas et al., 2017) for individuals with eating disorders, the ECHOMANTRA intervention offers these as an additional source of peer-based guidance and support to enhance the use of the workbooks. Finally, we offer families joint sessions with patients, carers and health professionals (via Skype) to support the transition phase. In addition to the potential benefits of a combined patient-carer approach for enhancing well-being among individuals with AN, the ECHOMANTRA intervention also contributes to the limited evidence base for technology-based tools to support AN recovery.

Study Aims

The aim of the TRIANGLE trial is to examine whether adding a novel skills-sharing intervention (ECHOMANTRA) to treatment as usual (TAU; inpatient treatment or intensive day-care treatment) improves patient and carer wellbeing, as well as increases carer skills and reduces carer burden 12 and 18 months after being randomised to the intervention. The primary outcome variable of the TRIANGLE trial is patient psychological wellbeing (anxiety, depression, stress symptoms) at 12 months post-randomisation.

The secondary objectives of the TRIANGLE trial include:

a) To assess the following regarding the hypothesised impact of TRIANGLE on patients:

    i.   Improved Body Mass Index (BMI) and reduced eating disorder symptoms in patients at 12 and 18 months post-randomisation.

    ii.   Improved work and social adjustment and motivation to change for patients at 12 and 18 months post-randomisation.

    iii.   Reduced number of days that patients spend in hospital at 12 and 18 months post-randomisation.

    iv.   Increased quality of life for patients at 12 months post-randomisation.

  v. Improved social functioning for patients, as reported by carers, at 12 months post-randomisation.

  vi. Intervention cost-effectiveness for patients at 12 months.

  vii. Improved psychological wellbeing (anxiety, depression, stress symptoms) for patients in the 18 months post-randomisation.

b) To assess the following regarding the hypothesised impact of TRIANGLE on carers:

  i. Reduced psychological distress, time spent caring, and improved skills in dealing with eating disorder symptoms in carers at 12 and 18 months after randomisation.

c) To assess patients and carers' feedback to the study protocol and intervention (i.e., feedback will be provided using a feedback form that includes open-ended as well as quantitative questions).

d) To evaluate the processes involved in facilitating change in patients and caregivers.

  i. To conduct exploratory analyses of whether baseline variables including BMI, level of autistic-like and obsessive-compulsive traits, motivation to change, work and social adjustment, duration of illness, type (inpatient/day-patient, voluntary/involuntary) and duration of admission and type of service used, predict overall treatment outcomes (i.e., patient psychological wellbeing, eating disorder symptoms, BMI, work and social adjustment, and quality of life) or act as moderators of treatment outcomes.

  ii. To conduct exploratory analyses as to whether early change (3- and 6-month post-randomisation) in patient's eating disorder symptoms, BMI, psychological wellbeing and importance and confidence to change predict patient's outcomes at 12 and 18 months. Patient BMI, eating disorder symptoms, psychological

wellbeing, and importance and confidence to change will be measured monthly, up to 18-month post-randomisation.

iii.   To assess the fidelity of the intervention using: (1) rating scales, (2) thematic analysis of online forum groups and Skype sessions (3), end-of-study feedback from patients and caregivers.

Method

Trial design

TRIANGLE is a multicentre, randomised, controlled, parallel group superiority trial that examines whether the addition of a guided skills-sharing intervention for patients and carers offered within the first few weeks of admission improves patient distress and other aspects of patient and carer wellbeing following intensive (inpatient/day-patient) treatment for anorexia nervosa. Patients that fulfil inclusion criteria will be invited to participate in the study once they are admitted for intensive treatment (whether as inpatients or day-patients). After provision of the consent form, the researcher or the on-site clinical study officer (CSO) will help participants to create their accounts and log-on to the study platform (created by Mindwave; http://mindwaveventures.com) to become familiar with it. Within 8 weeks from admission, participants will be invited to complete the baseline questionnaires and will then be randomly assigned to either (1) ECHOMANTRA in addition to TAU or (2) TAU only. Patients will be recruited from over 25 different specialist adult inpatient/day-patient eating disorder services in the UK. All participants will be monitored via short monthly tracking/feedback (to facilitate engagement) and progress assessment measures at 3, 6, 9, 12 and 18 months following randomisation (see Table 2). Participants in both conditions will receive visual feedback for some of their monthly assessment survey scores. The TAU-only (control condition) group will have no access to the intervention materials and guidance. At

the end of the study, individuals randomised to the TAU-only condition will be offered the self-help components of the intervention.

The ECHOMANTRA guided skills-sharing intervention includes materials for carers and patients. For carers, these materials include a workbook, a set of DVDs and 8 online, moderated and facilitated group discussion forums. For patients, these materials include a workbook, a set of video-podcasts ("vodcasts") and 8 online, moderated and facilitated group discussion forums. Additionally, patients will receive joint Skype sessions with their carer that will be facilitated by a participant-carer mentor (up to 6 sessions).

Randomisation

After screening and consent, patients and their carers will be randomised as a dyad with a ratio of 1:1 (stratified minimising on site and severity, defined by BMI < 15 at hospital admission) to receive either (i) access to the ECHOMANTRA intervention package in addition to TAU or (ii) TAU (control condition). This is performed with an 80% probability of allocating to the arm that reduces the imbalance; the allocation sequence will be generated dynamically so the next allocation will only become known upon actioning a request from the study site staff. A minimal number of research staff will be authorized to request randomisation and receive passwords for the randomisation system. Randomisation will occur by phone or email on weekdays within 24 hours, by the King's Clinical Trials Unit (King's CTU) based at the Institute of Psychiatry, Psychology and Neuroscience. The randomisation website is accessible at www.ctu.co.uk. Once the database has returned a dyad's allocation, no changes can be made. Those randomised to the intervention arm (i.e., ECHOMANTRA plus TAU) will then receive access to the intervention materials.

Clinicians treating AN and statisticians will be blinded to the condition allocated to the patient and their primary carer. Assessors will also be blinded by having research assistants each allocated to a sub-cohort of patients. It is possible that clinicians could elicit

(by questioning the patient) the exact content of the platform and hence the patient's group allocation. In the information provided to clinicians, we will explain that the project requires them to be blind to treatment unless there are reasons why that is not possible. We will ask clinicians to speculate as to which group the patient belongs at the end of treatment (i.e., at the 18-month assessment). Statisticians will be kept blind as long as possible; analyses requiring unblinding (e.g. those involving process variables such as the number of sessions attended) will be conducted last.

Participants

Patients aged 17 or over who are admitted to one of the participating specialist intensive units at the time of consenting (whether as inpatient or day-patient for at least 4 days/week), with a primary DSM-5 (APA, 2013) diagnosis of AN, or those with atypical or subclinical AN, will be approached to participate. Patients will then be asked to nominate a carer and the researcher will invite that carer to participate in the trial. Inclusion criteria for patients are as follows: (a) aged 17 years or older, (b) DSM-5 diagnosis of Anorexia Nervosa, or atypical or subclinical AN, with a body mass index (BMI) of ≤ 18.5 kg/m^2, (c) with a carer willing to participate (we use a broad definition of "carer" to include family and/or friends willing and able to provide support), (d) informed consent signed within 2 months from admission, and (e) ability to access an electronic device (e.g., mobile phone, computer, laptop, tablet) and the internet in order to access the study website. Exclusion criteria for patients include the following: (a) insufficient knowledge of English, (b) severe mental or chronic physical illness needing treatment in its own right (e.g., psychosis, diabetes mellitus, cystic fibrosis etc.), (c) patient is pregnant, or (d) the patient-carer dyad has previously received treatment involving the ECHOMANTRA materials (e.g., as part of the MANTRA trial or the CASIS study; Hibbs et al., 2015a; Schmidt et al., 2015).

The number and proportion of subjects with adverse events will be recorded. If patients need to be readmitted to hospital whilst they are participating in the trial because their physical health has deteriorated, they will continue with their participation in the study. The number of days that patients spend in hospital throughout the study will be recorded. It is unlikely that carers will be withdrawn from the study for clinical reasons.

Sample size

A sample size of n=380 dyads will be sufficient to determine clinically significant improvements under ECHOMANTRA compared to TAU-alone. Based on past research, recruitment is feasible in two years (Hibbs et al., 2015a). This calculation is based on wishing to detect an effect size of Cohen's $d = 0.40$ for patient distress (depression, anxiety, and stress; DASS-21) at 12 months with 90% power using a two-tailed t-test at a significance level of 0.05, and allowing for attrition rates observed in previous studies (i.e., 30% at 12 months). Our estimation of effect size is based on our previous research (Hibbs et al., 2015a; Magill et al., 2016) along with our assessment of clinically significant change. The iMANTRA trial, which only targeted the patient, achieved an effect size of $d = 0.64$ on DASS-21 at 12 months (NIHR PGfAR grant report by Schmidt et al., 2015). The CASIS trial, which only tested the parent/partner component of the intervention, found an effect on patient DASS-21 of $d = 0.17$ at 12 months (Hibbs et al., 2015a) and $d = 0.25$ at 24 months (Magill et al., 2016); thus $d = 0.40$ is a conservative estimate of the effect size we are hoping to achieve with this combined intervention. The DASS-21 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 in TAU arm at 12 months, n=57), we expect our target population to be in the lower end of the severe range of distress at 12 months under standard treatment. An improvement by 11 points

would shift the distress into the middle of the moderate range and would, therefore, be considered clinically significant.

Recruitment

For patients, the medical team from the NHS/independent hospital will screen the patients admitted to their specialised units, whether as inpatient or day-patient. They will then inform the clinical study officers or research assistants in their team, who will approach potentially eligible participants and obtain written informed consent. The names and contact details of prospective carer participants will be obtained from the patient participants. The local investigator at the NHS/independent hospital or the clinical study officer will start the process of recruitment and consenting of carers to participate in the trial (see Figure 1 for a flowchart describing the phases and timings of the study; see Figure 2 for the progression through the phases of the trial for the two arms, including enrolment, intervention allocation, and assessments).

Treatment arms

Treatment as Usual (TAU). The group allocated to the TAU-only (control) condition will be asked to complete assessments on the same online platform (Mindwave) as those in our intervention condition. We chose not to use a standardised comparison treatment as (1) there is no evidence on which to base such a choice, and (2) this would require a change in practice in a diverse range of settings and the resource for the management of this (including training, supervision and quality control) was not feasible. We have therefore chosen to allow centres to follow their own procedures (TAU). We will stratify our analyses by centre, which will adjust for any bias accordingly.

For TAU inpatient care or intensive day-clinic care programs, there are quality standards that usually involve a multidisciplinary team approach (dietician, psychologist, occupational therapist, physician, family therapist, social worker, nurse) (Royal College of

Psychiatrists, 2013). We have found in our previous study that there is a large amount of variation in length of stay of inpatient care although admission and discharge weights are similar (Goddard et al., 2013). For TAU aftercare for anorexia nervosa, there is very little available information. It often includes monitoring of physical risks, dietetic assessment and advice and some form of individual outpatient therapy (commonly CBT, interpersonal psychotherapy or focal psychodynamic therapy) or a transition to day-care. In our pilot study (CASIS), we found that less than 50% of patients had outpatient support for the year after discharge (which was recommended by the NICE guidelines) (Hibbs et al., 2015a). Often there is a split between services because inpatient care is paid for by NHS England and outpatient care is provided by clinical commissioning groups. The teams involved therefore can often differ. For example, many inpatient beds (>300) are in independent hospitals, but paid for by NHS England. Given the variability in TAU aftercare, we will ask the inpatient/day-patient clinical sites to inform us about the responsible clinical team after discharge. We will inform the aftercare clinical team about what participation in TRIANGLE involves and suggest that they can continue with usual care. We will also solicit precise information about the treatment both offered and received through questions to professionals and patients. These differences will be assessed and taken into account when analysing and interpreting findings.

Active treatment: TAU plus patient and carer skills-sharing intervention (ECHOMANTRA). The aim of these materials is to transfer the learning and progress gained from the intensive inpatient/day-patient experience into the home-context via tools which can be accessed where, when, and as often as needed. The behaviour change strategies we teach are the standard approaches recommended by the NICE guidelines (NICE, 2004; NICE, 2017). The materials include workbooks and videos based on the cognitive interpersonal model of anorexia nervosa (Schmidt & Treasure, 2006; Treasure & Schmidt,

2013). Broadly speaking, the materials aim to promote reflection, planning and new learning to modify the eating disorder habits and optimise socio-emotional functioning and interpersonal relationships. Patients are encouraged to ask the carer they have nominated (e.g., a family member or friend) to support their work and to use the workbooks and DVDs as a guide.

The patient "vodcasts" (brief video podcasts) map onto the patient workbook 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 the 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.

Patients will be invited to participate in moderated group discussion forums to explore and reflect on these materials (8 sessions: at least 4 during admission, and at least 4 after discharge from inpatient/day-patient care). Each session lasts 60 minutes and is themed (denoted by session A – session H) following the structure of the patient workbook (see Table 1). Staff members (including some with experience from the UK charity "Beat Eating Disorders" (BEAT) and grade 5 research assistants) will facilitate and moderate the forums. The moderator checks each message against the forum rules (e.g., making pro-illness comments; disclosing personal information) before it is published (i.e., visible to the forum participants). The facilitator encourages discussion around the information and exercises proposed in the workbook and will receive weekly supervision by our study team. A clinical supervisor will also be available during the forums, should the moderator and/or facilitator have any concerns about participant safety. Group sessions will be open and patients will be allocated on a rotational basis depending on caseload; patients may take part in as many

groups as desired, and two group sessions will be offered weekly for participation. The text of the forums will be recorded, saved and used for team supervision.

Carers allocated to the ECHOMANTRA intervention group will receive a carer workbook and gain access to a library of podcasts and DVDs (www.succeedfoundation.org) produced by a recovered patient and the research team. The workbook and the DVDs offer a skills training programme including: training in stress management, communication (motivational interviewing) and strategies to reduce accommodation and expressed emotion and to increase extinction training and new habits at home via effective social support. Carers are also invited to attend at least 8 online group forums (4 during patient admission and 4 after patient discharge) to discuss the information and exercises proposed in the workbook. The structure and timing of the forums is the same as indicated for patients above.

Patients and carers will also receive up to 6 joint Skype sessions with a mentor (a "participant-carer mentor") with the aim of enlisting social support and generating perspective-taking to attain behavioural goals. Three experienced health professionals will be appointed and trained as mentors for the joint Skype sessions. The mentors will be trained and supervised in the new Maudsley Model of family work (including motivational interviewing and behaviour change strategies) via a 3-day face-to-face interactive workshop followed by two 3-day booster sessions led by a professional with 25 years of expertise in the field. Audiotapes will be used for weekly clinical supervision by experienced clinicians and supervision and mentor support will also provided by email and telephone. Mentors will also be asked to report their own adherence, acceptability and satisfaction with delivery. They will only be assigned study patients/carers once they have obtained a minimal level of competence with training samples (i.e., individuals not within the proposed study). Adherence and fidelity to the intervention model will be monitored by assessing the electronic records of the Skype sessions.

Assessment

Adherence. Monetary rewards and free registration to attend the annual national carers' conference will be offered to participants on completion of the assessments (our pilot studies suggest that these increase protocol adherence). In order to facilitate good assessment rates, several strategies will be used: (a) participants will be cued by email to complete the computerised self-report measures, (b) participants will be requested to completed regular surveys and will be provided with a visual representation of their scores over time, and (c) the patient's clinical team will be contacted, with permission, to provide additional data (such as weight).

Blindedness. Behavioural and clinical outcome measures will be conducted blind to treatment allocation. Participants will be reminded at the beginning of each assessment not to reveal their treatment allocation to the assessor. To test the success of blinding, assessors will be asked to guess the treatment group of the participants after the end of the study. Data analysts will also be blind to treatment condition.

Measures

Assessments will be conducted for patients, their carers, their Skype joint-session mentors, and clinicians (see Table 2 for the assessment schedule). All of the assessment materials will be available online.

Patient assessment. Patients complete the following assessments:

- Socio-demographic questionnaire.

- Depression, Anxiety and Stress Scale - short (DASS-21; Lovibond & Lovibond, 1995). A 21-item self-report measure that assesses the related but distinct symptoms of depression, anxiety, and stress. Research supports the reliability and validity of the DASS-21 in both clinical and non-clinical samples (Antony, Bieling, Cox, Enns, & Swinson, 1998). This is the primary patient outcome measure.

- Weight, height and BMI will be obtained from clinical measurement and from patients, monthly, up to 18 months post randomisation.

- The Autism Spectrum Quotient (AQ-10; Allison, Auyeung, & Baron-Cohen, 2012). A brief measure to assess autism spectrum traits as a marker of social functioning.

- The Obsessive Compulsive Inventory (OCI-R; Foa et al., 2002). Assesses the frequency and associated distress of seven obsessive-compulsive symptom domains.

- Eating Disorder Examination-Questionnaire (EDE-Q; Fairburn & Bèglin, 1994). Assesses eating disorder symptoms with good reliability and validity (Luce & Crowther, 1999).

- Work and Social Adjustment Scale (WSAS; Mundt, Marks, Shear, & Greist, 2002). Assesses patients' perceptions of impairment in everyday work and social functioning.

- Motivation Ruler. Visual analogue scales to measure confidence and importance to change eating disorder symptoms.

- EUROQOL (or EQ-5D; Herdman et al., 2011). This 5-level health status measure was developed by a European consortium for use in health economics. It offers a simple index of health-related quality of life.

- Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001). This is a well-established method of data collection linked to cost analysis. A reduced self-report version previously used in eating disorder research assesses the use of specialist and generic health services, education or employment.

- Hospital episode statistics. These assess days spent in hospital up to 18 months post-randomization.

- Participant Feedback Form. This assesses participants' experiences in the study. For those in the ECHOMANTRA plus TAU (treatment) arm, the form also includes

Likert scales and areas for free expression to measure the use and acceptability of the intervention components.

- Post-joint session survey. These self-developed visual analogue scales solicit feedback from participants about their experiences after each patient-carer joint Skype session.

Carer assessment. Carers complete the following assessments:

- Demographics questionnaire.

- Depression, Anxiety and Stress Scale-short (DASS-21; Lovibond & Lovibond, 1995). As described above.

- The Caregiver Skills scale (CASK; Hibbs et al., 2015b). This assesses skills helpful in managing eating disorder behaviours.

- Strengths and Difficulties Questionnaire (SDQ; Goodman, 2001). This assesses broad social functioning (peer problems, pro-social difficulties, hyperactivity, emotional problems, and conduct problems) for the patient and is completed by informants (in this case, the measure will be completed by the primary carer who is participating in the trial).

- Participant Feedback Form. As described above.

- Post-joint session survey. As described above.

    Mentor assessment. Mentors complete the following measures:

- Post-joint session surveys. As described above; administered to mentors after completing each Skype session with the patient-carer dyad.

- Mentor Feedback Form. Includes visual analogue scales and areas of free expression to measure intervention fidelity and satisfaction levels in delivering the intervention.

    Clinical Team Assessment. When feasible, the clinical team at the hospital or the aftercare team will provide patient information on a monthly basis, from admission up to 18

months post-randomisation (e.g., BMI, admission date, discharge date, day-care or inpatient care, patient under Mental Health Act, patient transferred from another service, family involvement in treatment, days spent at home, and types of treatment received).

Data analysis

All formal analyses for the evaluation of clinical effectiveness will be carried out following the intention-to-treat principle by the trial statistician who will be kept blind to treatment allocation as long as possible (dealing with potential mentor effects in the ECHOMANTRA arm will require un-blinding at some point). The same modelling approach will be used for primary and secondary outcome variables to estimate differences between trial arms at the post-randomisation assessment time points.

Linear mixed models assuming normal distributions will be used to simultaneously model continuous outcome variables at baseline, and at various post-randomisation time points (e.g., for primary patient outcome, DASS-21). The models will be parameterised, such that a separate group effect is estimated at each time point. Models will always include baseline values of the variable under investigation as a covariate to increase power. They will further include effects of time (3, 6, 12, 18 months), trial arm (ECHOMANTRA plus TAU or TAU only) and a group x time interaction. Models also condition on variables that may be found empirically to predict attrition, and on minimisation factors (site and BMI). To detect baseline predictors of missingness, a forward logistic selection procedure will be used. Finally, the linear mixed models will fit a random intercept that varies at the level of the mentor to account for mentor effects if necessary, and it will fit an unstructured covariance model to account for the correlation between the repeated measures (baseline and post-randomisation). The modelling is valid (i.e., provides unbiased estimates of group effects) provided the missing data generating process is missing at random (MAR, here meaning that trial arm, time, baseline values and the identified predictors of missingness can drive loss-to-

follow up). Furthermore, missing values in baseline variables can be singly imputed (White & Thompson, 2005). We will investigate whether non-adherence with ECHOMANTRA is predictive of later drop-out from the trial. Should this be the case, then we will employ multiple imputations to provide an analytical approach that can accommodate such a MV generating process.

Analysis of continuous secondary outcomes will follow the same approach; with distributional assumptions checked and transformations applied as required. Analyses of non-continuous secondary variables will be based on more appropriate distributional assumptions. For example, re-admission rates will be analysed using a Poisson model.

Economic evaluation. Service use, lost employment/education and costs will be described and compared between the two groups. Public sector costs will be estimated by combining patients' service use data with unit costs to derive costs by provider agency and total costs per person. Lost employment costs will be estimated based on days missed from work due to AN, and average wage rates. Cost data are likely to be skewed, so we will use bootstrapping methods to estimate 95% confidence intervals around the mean total cost differences. We will assess relative cost-effectiveness of the intervention and TAU using public sector costs and DASS-21 at the 18-month follow-up assessment. We will also undertake a cost-utility analysis using public sector costs and health related quality of life gains estimated from the EQ-5D (quality adjusted life years or QALY). If costs are higher for one group and outcomes are also greater, we will construct incremental cost-effectiveness ratios (ICER) to show the cost per extra unit for outcome gained (DASS point or additional QALY) with the uncertainty plotted on cost-effectiveness planes. From these data, we will generate cost-effectiveness acceptability curves (CEAC), using the net-benefit approach, to indicate the probability that one option is more cost-effective for different values placed on a

one-point outcome gain. The range of values used will be within £0 to £100,000, which includes the QALY threshold used by NICE.

Qualitative Analysis Plan. Qualitative data will be derived from participant feedback forms, online discussion forums and joint Skype sessions. A thematic analysis will be used to analyse data from both the focus groups and the acceptability measures. Thematic analysis is a commonly used qualitative method for identifying, analysing and reporting patterns or themes within a data set (Braun & Clarke, 2006). This involves reading the data several times to gain familiarity and identify potential patterns. Initial codes will then be generated and incorporated into meaningful clusters of data and entered into the computer software programme QSR Nvivo (1999). Coding will follow a theory-driven process with specific research aims in mind. A thematic framework will be generated and emerging relationships reflected in a group of higher and lower order themes. Data will be coded by an independent, second coder to establish a thematic framework, and then presented to the PPI panel for further clarification. Researchers will be blind to group allocation whilst carrying out the analysis.

Discussion

The TRIANGLE trial investigates whether the ECHOMANTRA intervention can improve outcomes (in comparison to only receiving treatment as usual) following intensive care for anorexia nervosa. We are primarily interested in assessing the outcome of patient distress (i.e., anxiety, depression, and stress symptoms) given that ECHOMANTRA focuses on remediating patient's socio-emotional difficulties by strengthening social connection (Schmidt and Treasure, 2006; Treasure & Schmidt, 2013; Oldershaw, Lavender, Sallis, Stahl, & Schmidt, 2015). We also assess patient and carer outcomes across other clinically significant domains such as eating disorder symptomatology and BMI in patients, and illness burden and accommodating behaviours in carers. ECHOMANTRA is designed to be

affordable, scalable and has the potential for wide reach. Technologies such as computerised assessment and feedback, moderated and facilitated online discussion forums, Skype-based joint sessions with carers and patients are used to increase engagement.

Challenges

This trial builds on several pilot studies that have used the elements of ECHOMANTRA in various forms. The knowledge acquired from these pilot studies has enabled us to anticipate and plan to overcome many of the identified challenges. The following list highlights what has been learned and how this has informed the protocol.

i. We have engaged a large proportion of the NHS England units in our previous studies. In this study, we have recruited the majority of independent units and other NHS units. This will ensure that we can recruit enough participants to obtain the sample size needed to determine clinically significant outcomes and explore moderators and mediators of change. This will be the largest RCT study of intensive care to date.

ii. This study requires engagement of both carers and patients. Previously we have found there to be a trend for less adherence to the study from those allocated to the TAU-alone control condition. We will use the study platform to increase engagement, by providing automated reminders about the assessments and graphic feedback from assessments. Finally, we will provide monetary recompense in recognition of the work involved.

iii. We have kept the outcome measures to a minimum, in order to reduce participant burden.

iv. We have improved the quality and content of the multimedia aspects of the intervention. Thus, we now have professionally produced DVDs for carers. We hope that this will maximise the use of these materials.

v. We have adapted the workbooks to emphasise the new understanding about social emotional processing that has informed the interpersonal element of the model, such as the attention to threat and limited emotional expressivity (Caglar-Nazali et al., 2014; Cardi et al., 2015b). We have incorporated feedback, imagery and metaphors from patients and carers to make the materials more user-friendly.

vi. We have added more detailed interpersonal outcome measures in order to validate this new adaptation to the model.

vii. Given the variability in inpatient/day-patient TAU (e.g., length, goals), we have decided to use a standardised measure, time from baseline and up to 18 months post-randomisation to evaluate the outcome.

viii. We will use information from patients to establish service use. We will also use National Health statistics to establish number of days spent in hospital.

ix. We are using the health economic measures advocated by NICE so that the data are available in a form that can be compared with other conditions and so can be used for service planning.

x. Our pilot data suggest that carers do not benefit from coaching (Hibbs et al., 2015a). Therefore, we will offer only a minimal degree of support for this. Instead, more guidance will be provided by peers and for the joint work.

xi. Our pilot data suggest that although "peer" mentors do an excellent job in providing support for current patients, in order to continue their development, they need to move on to new challenges (unpublished data). A more sustainable approach is therefore to train basic level psychologists who can benefit from the experience in their further careers. This follows the approach used in Improving Access to Psychological Therapies (IAPS) services in the UK.

The Place of New Technologies

A review of potential application of new technology in eating disorder interventions concluded that few applications developed thus far follow evidence-based principles for treatment and fail to capitalize on the unique features such as opportunities for repeated self-assessment (Ambwani, Cardi, & Treasure, 2014). Similarly, a review of mobile applications concluded that at present they do not have optimised designs (Fairburn & Murphy, 2015; Fairburn & Rothwell, 2015). So far, there have been four randomised controlled trials of computerised interventions for bulimia nervosa which show promise (Fairburn & Murphy, 2015). ECHOMANTRA is a novel mixed method/hybrid intervention which has a strong component of peer and social support and is theoretically-grounded in risk factors. Testing this intervention could make a significant contribution to the limited evidence base for the use of technology to support ED recovery, particularly for anorexia nervosa.

Conclusion

We hope that the findings from the TRIANGLE trial can optimise inpatient/day-patient aftercare by maximising collaboration between professionals and the key parties involved. Furthermore, we will have more information about the factors that maintain the illness for those with a severe/enduring illness.

Trial Status

The trial commenced in November 2016.

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Table 1

ECHOMANTRA intervention: Aims and materials for online discussion forums and joint patient-carer Skype sessions in TRIANGLE.

POST RANDOMISATION	<u>Aim</u> of this phase: to prepare for discharge with identification of goals and implementation of goal setting strategies. <u>Materials</u>: workbook, vodcasts and 4 online group discussion forums.
Forum A	Introduction and assessment of motivation. Discussion around the impact of the eating disorder on the brain and the body. Discussion of behaviour change strategies.
Forum B	Discussion around the impact of the eating disorder on social relationships. Discussion of behaviour change strategies.
Forum C	Identification and set-up of behavioural goals, with a particular focus on eating- and food-related goals.
Forum D	Discussion and implementation of goals setting strategies.
DISCHARGE	<u>Aim</u>: Target goal hierarchy and support motivation to change and behaviour change. <u>Materials</u>: 4 online group discussion forums. Up to 6 patient-carer joint Skype sessions with a mentor.
Forums E - H	Revise goal setting and behaviour change strategies. Discuss strategies to support motivation to change and behaviour change. Re-visit implementation of some of the earlier concepts from the workbook.
Patient-carer joint Skype sessions	Identification of behavioural goals that will allow patients and carers to use the knowledge and to practice the skills acquired during the online forums.

Table 2 *Assessment schedule for TRIANGLE: Self-reports measures that patients, carers, mentors and clinical teams will be required to complete from baseline up to 18 months post-randomisation*

Participant status	Baseline assessment	Post-randomisation timeline					
		Monthly- up to 18 months	3 Months	6 months	9 months	12 months	18 months
Patient	Socio-demographic questionnaire BMI DASS-21 EDE-Q Motivation Ruler WSAS AQ-10 OCI EQ-5D CSRI	BMI Likert scales on social connection	DASS-21 EDE-Q BMI Motivation Ruler	DASS-21 EDE-Q BMI WSAS Motivation Ruler	DASS-21 EDE-Q BMI Motivation Ruler	DASS-21 EDE-Q BMI WSAS Motivation Ruler EQ-5D CSRI	DASS-21 EDE-Q BMI WSAS Motivation Ruler Participant Feedback Form
Carer	Socio-demographic questionnaire DASS-21	Likert scales on social connection	DASS-21	DASS-21 CASK	DASS-21	DASS-21 CASK SDQ	DASS-21 CASK Participant Feedback

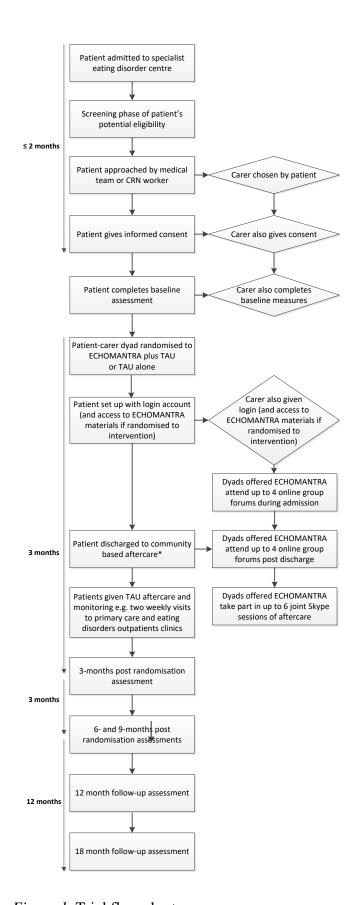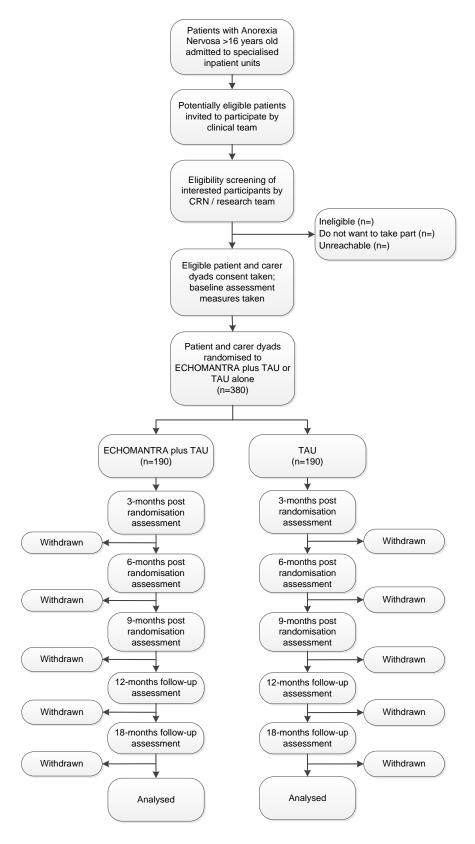|						
	CASK SDQ					Form
Mentor						Feedback Form
Clinical team		Clinical team monthly assessment				

Figure 1. Trial flow chart.

Figure 2. Consort diagram illustrating the progression through the study of the ECHOMANTRA + TAU and TAU-only groups.