Experienced Carers Helping Others (ECHO): Protocol for a Pilot Randomised Controlled Trial to examine a psychoeducational intervention for adolescents with anorexia nervosa and their carers.

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Abstract

Experienced Carers Helping Others (ECHO) is a psychoeducational intervention for carers of people with eating disorders. The aim of this paper is to describe the theoretical background and protocol of a pilot multi-centre outpatient randomised controlled trial that will investigate the use of the ECHO intervention (alone or with telephone coaching) for both the carers (usually parents) of adolescents (age 13-21) with anorexia nervosa (AN) and the adolescents themselves. Adolescents with AN or Eating Disorder Not Otherwise Specified – AN subtype (EDNOS-AN) and carers will be recruited from eating disorder outpatient services across the UK (N = 38). Carers will be randomly allocated (stratified by site, sufferer's age, and illness severity) to receive 'ECHOc' guided self-help (in addition to treatment as usual), 'ECHO' self-help only (in addition to treatment as usual) or treatment as usual only. Primary outcomes will be a summary measure at 6- and 12- month follow-up of Short Evaluation of Eating Disorders (SEED) monthly assessments. Secondary outcomes will be other relevant clinical outcomes for patients (e.g. distress, obsessive-compulsive traits), caregiver distress and behaviours (e.g. expressed emotion, accommodating and enabling), and psychosocial measures and health economic data at 6- and 12- month follow-up. Therapist effects and the feasibility of delivering ECHO (with telephone coaching) to an acceptable level of competence, as measured by the Motivational Interviewing Treatment Integrity 3.1.1 Code, will also be examined. The findings from this study will be used in preparation for executing a definitive trial, powered to determine the impact of the preferred variant of ECHO, to improve treatment outcomes for AN at an early stage of illness. Trial Registration ISRCTN83003225 - Experienced Carers Helping Others (ECHO)

Keywords
Anorexia nervosa; eating disorders; carers; adolescents; family intervention; treatment; outpatient; randomised controlled trial; skills training; motivational interviewing

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Background

Anorexia nervosa (AN) is a severe psychiatric illness with a protracted course (Stoving, Andries, Brixen, Bilenberg, & Horder, 2011; Wentz, Gillberg, Anckarsater, Gillberg, & Rastam, 2009) and associated with high healthcare costs (Krauth, Buser, & Vogel, 2002). The National Institute of Health and Clinical Excellence (NICE) guidelines recommend that most people with an eating disorder (ED) should be managed on an outpatient basis in the first instance (NICE, 2004). The peak age of onset is in mid adolescence (Currin, Schmidt, Treasure, & Jick, 2005; Micali, Hagberg, Petersen, & Treasure, 2013) and therefore family members usually take on a caregiving role. However a meta-analysis of several aspects of carer functioning obtained from a systematic review concludes that carers find this role burdensome and distressing (Anastasiadou, Medina-Pradas, Sepulveda, & Treasure, submitted, 2014; Zabala, Macdonald, & Treasure, 2009). Families request information and help with this role (Haigh & Treasure, 2003).

Family therapy is one way of involving families in treatment. To date, it is the most effective form of intervention in the early phase of the illness (less than three years duration), according to the results of a Cochrane (Fisher, Hetrick, & Rushford, 2010b), and later, systematic review (Couturier, Kimber, & Szatmari, 2013). However, this type of involvement is less effective in those with a longer duration of illness (Fisher, Hetrick, & Rushford, 2010a). Moreover, family therapy is not acceptable for all families. Other types of interventions that involve the family have been developed such as "separated family therapy" in which the patient is seen individually and the parents are seen in parallel (Le Grange, Eisler, Dare, & Russell, 1992). This type of intervention was as effective as family therapy and was particularly helpful for families with high expressed emotion (Eisler, et al., 2000). A further adaptation is multi-family therapy (Asen, 2002). In this form of therapy several families are seen as a group for a week (9-5). Preliminary evidence suggests that this form of intervention is as effective as family therapy (Eisler, 2005). It is, however, demanding on family time and because the group format can be somewhat inflexible.

Other approaches that have been used in working with families are based on a theoretical framework which has the basic assumption that if carers are provided with skills and education to understand the "enigma" of AN, then they can form part of the therapeutic team. We have undertaken a systematic review of the literature relating to this type of intervention (Hibbs, Rhind, Leppanen, & Treasure, 2014a, submitted). A variety of implicit and explicit theoretical maintenance models have been employed. Thus, there have been interventions based on a form of exposure model that teach carers how to give meal support (Cairns, Styles, & Leichner, 2007). Others teach specific skills to produce behaviour change such as motivational interviewing (MI) (Goddard, Macdonald, Sepulveda, et al., 2011) or Cognitive Behaviour Therapy (CBT) (Grover, Naumann, et al., 2011; Grover, Williams, et al., 2011). Some work on the possibility that the carers coping pattern is suboptimal (Pepin & King, 2012) which leads to high anxiety which in turn is mirrored by the
person with the ED and serves to escalate symptoms (Goddard, Macdonald, Sepulveda, et al., 2011). Others are based on a model that suggests that high expressed emotion such as criticism and over protection may maintain ED behaviours (Butzlaff & Hooley, 1998; J. Treasure, et al., 2008). Yet others suggest that accommodation and enabling behaviours serve to maintain ED behaviours (Sepulveda, Kyriacou, & Treasure, 2009; Treasure, et al., 2008). Some of the models are complex and contain all of these features. The results of the meta-analysis of carer outcomes from the systematic review show a moderate sized reduction in carer burden and distress, expressed emotion and accommodating behaviours (Hibbs et al., in preparation, 2014a). However, very few high quality studies have examined the impact of interventions offered to carers on individuals with an ED themselves (e.g. Hibbs, 2014b, in preparation; Whitney, et al., 2012).

Experienced Carers Helping Others (ECHO) is a novel intervention for carers based on the cognitive interpersonal maintenance model of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013). One element of this model is that interpersonal factors (such as those described above) can develop within families and maintain the illness (Schmidt & Treasure, 2006; Treasure, et al., 2008) and inadvertently hinder recovery. Empirical evidence to support the model is emerging (e.g. Goddard, Macdonald, & Treasure, 2011; Goddard, et al., 2013). The ECHO intervention targets modifiable elements of caregiving such as high expressed emotion and accommodating and enabling behaviours and teaches the skills of MI as a means of providing calm and compassionate meal support (Treasure, et al., 2007).

The cognitive interpersonal maintenance model of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013) also includes individual vulnerabilities such as aspects of cognitive style that are thought to contribute to the maintenance of the illness. For example, in general, people with EDs have good cognitive abilities with superior attention to detail but they sometimes show inefficiencies in set shifting (Lang, Stahl, Espie, Treasure, & Tchanturia, 2013; Lopez, et al., 2008). These traits can manifest as an obsessive compulsive personality which is associated with a poorer response to treatment (Crane, Roberts, & Treasure, 2007). These traits are also present in people with autistic spectrum disorders and several studies have found that people with AN have high scores on the Autism Spectrum Questionnaire (Baron-Cohen, et al., 2013; Hambbrook, Tchanturia, Schmidt, Russell, & Treasure, 2008; Tchanturia, et al., 2013). Individuals with AN with social and communication difficulties and autistic spectrum traits have been found to have a poorer prognosis (Anckarsater, et al., 2012). First degree relatives may share obsessive compulsive personality traits (Lilenfeld, Wonderlich, Riso, Crosby, & Mitchell, 2006). These traits may make it difficult for both the patient and carer to have a flexible response to the development of ED symptoms and worsen the prognosis.

Another facet of the cognitive interpersonal maintenance model of AN (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013) is the pro AN beliefs and behaviours that can develop as a consequence of the illness (Serpell, Teasdale, Troop, &
Treasure, 2004). It is possible that these can be particularly pronounced if other members of the family have their own ED problems. There is evidence that ED are common in first degree relatives of patients and that ED run across generations (Kanakam, Krug, Raoult, Collier, & Treasure, 2013; Lilenfeld, et al., 1998; Strober, Freeman, Lampert, Diamond, & Kaye, 2000). Furthermore, carers’ own history of eating problems is associated with caregiver distress (Goddard, et al., 2013). Therefore, family history of an ED, may moderate response to treatment.

The ECHO intervention

ECHO is a guided self-help skills training intervention developed to meet some of the complex unmet needs of carers. The intervention combines psychoeducation with skills-training by ED specialists. Initially the elements of ECHO were delivered in the form of workshops which were found to reduce carer distress (Sepulveda, Lopez, Todd, Whitaker, & Treasure, 2008) and expressed emotion (Sepulveda, et al., 2010). These also produced positive effects for the patients themselves (Goddard, Macdonald, & Treasure, 2010). As a ‘next step’ the training materials were synthesised into a self-help intervention (book and set of DVDs) to enhance accessibility, improve the cost-effectiveness and aid dissemination. Carer coaches (individuals with personal or professional experience in caregiving for someone with an ED) were trained to act as telephone mentors in order to provide guidance in the implementation of the materials. The coaches were trained to use MI as a communication style and to use the model of carer stress and the interpersonal maintenance model as a template of behaviours for possible change. This was found to be a feasible and acceptable form of intervention (Goddard, Macdonald, Sepulveda, et al., 2011) however the “dose” of guidance given (three sessions for one carer) was insufficient to provide benefit. A more rigorous training programme with a manual to structure the sessions and an enhanced programme of supervision and monitoring was introduced to improve the quality assurance of the intervention. The duration of coaching was increased to 10 sessions per family. In a pilot randomised trial, this was used as an intervention to support carers of patients, with severe and enduring ED, admitted for inpatient care (see Goddard, et al., 2012). Following the intervention, carer burden, time spent caregiving, and unhelpful carer behaviours were reduced (Hibbs, 2014b, in preparation). Given that patients at this stage of illness are resistant to most forms of treatment (Hay, Touyz, & Sud, 2012; Wonderlich, et al., 2012), small signs of improvement within this group, such as less use of services, and patients reporting an improved relationship with their carer, is encouraging (Hibbs et al., in preparation 2014b) A common comment from carers was the wish to have had access to the intervention at an earlier stage of the illness.

The current trial

The primary aim of the current study is to investigate the use of the ECHO intervention (guided, not guided) for adolescents with AN at an early stage of illness. This randomized controlled trial compares three treatment conditions: i) the ECHO
intervention as guided self-help (ECHOc), in addition to treatment as usual (TAU); ii) the ECHO intervention as self-help only (ECHO, in addition to TAU; and iii) TAU. This design will explore the additional use of coaching (the 'guided' component of guided self help) relative to providing self-help materials alone. For carers and patients, the primary hypotheses refer to outcomes at the 6- and 12- month follow-up time points.

**Methods and Design**

**Hypotheses**

**Primary hypotheses**

1. At 6- and 12-month follow-up, patients with carers allocated to the intervention arms (ECHO/ECHOc) will have a more rapid and stable reduction in AN symptoms compared to TAU alone, as measured by the Short Evaluation of ED (SEED).

2. At a 6- and 12-month follow-up, patients with carers allocated to the guided intervention (ECHOc) will have more rapid and stable reduction in AN symptoms compared to ECHO only (ECHO), as measured by the SEED.

**Secondary hypotheses**

3. The cost of support (societal and individual) will be lower for patients and carers in the ECHO/ECHOc arms than the TAU group at 6- and 12-month follow-up.

4. Carers who receive ECHO/ECHOc will report a greater reduction in caregiving burden (objective [i.e. cost of illness, contact time] and subjective [i.e. distress]), and accommodation and enabling, compared with TAU at 6- and 12-month follow-up.

5. A reduction in maintaining variables accommodation and enabling behaviours and caregiving burden will mediate outcomes for patients.

6. Obsessive compulsive and autistic traits in patients and carers will moderate the effect of ECHO/ECHOc on carer and patient outcomes.

7. Parental attitude and behaviour towards food, weight and shape will moderate carer and patient outcomes.

8. ECHOc will be delivered to an acceptable level of competence, as measured by the Motivational Interviewing Treatment Integrity (MITI 3.1.1) (Moyers, Martin, Manuel, Miller, & Ernst, 2010).

9. There will be therapist effects (level of experience, carer coaches versus professional affiliation coaches) on efficacy of ECHOc coaching intervention.

**Research Plan**

**Ethics and governance**

Main ethics approval has been granted by the Northwick Park Hospital Ethics Committee (11/H0724/4). Site-specific ethics and governance approval has been
granted on all participating sites and this study adopted by the Mental Health Research Network (MHRN).

**Trial design**
This is a pragmatic 3-arm multi-centre parallel group pilot RCT. The study design is shown in Figure 1. Consenting carers of patients who meet the eligibility criteria will be randomly allocated to receive ECHO (in addition to TAU), ECHOc (in addition to TAU) or TAU only. The delivery of ECHO and ECHOc is managed by the co-ordinating centre. Patients and their carers will be recruited from adolescent and ED National Health Services (NHS) providing ED specialist outpatient care to individuals with an ED aged 13-21 inclusive across the UK. This evaluation will investigate ECHO and ECHOc in a pragmatic setting, reflective of outpatient care for ED in the UK. Data will be collected at baseline (referral to outpatient services) and follow-up time points (6- and 12-months).

**INSERT FIGURE 1 NEAR HERE**

**Randomisation**
Following recruitment of patients and their carers, informed consent and completion of family baseline assessment (after initial assessment at the centre), carers will be randomly allocated to one of the three trial arms (ECHO, ECHOc or TAU) within 24 hours using the King’s Clinical Trials Unit (King’s College, London). A database will hold the basic details required for randomisation (centre, severity of illness [weight/height; presence of compensatory behaviours; presence of previous hospital admissions], date-of-birth, initials and unique patient number) to facilitate subsequent verification. Stratified randomisation using centre (3+) and illness severity (weight/height ratio) is employed. Minimisation with a random component is used. The first $n$ cases ($n$ will not be disclosed) are allocated randomly to further enhance allocation concealment. Once the database has returned a patient’s group allocation, no changes can be made. Those randomised to the TAU group will be offered the intervention (ECHOc) on completion of the study. The stratification factors (study site, age and illness severity) will be adjusted for in the analysis. All correspondence with carers on randomisation is by post.

**Researcher blinding**
This is a single blind study. The two lead researchers (CR and RH) are each individually responsible for a selection of the participating sites. Each manages the randomisation for their allocated sites and is blind to the group allocation of the sites managed by the other researcher. Assessment is co-ordinated so that researchers will only conduct interviews with those for whom they are blind to treatment allocation.

**Participating sites**
This project is a multi-centred trial involving 38 UK ED services providing outpatient care for people aged 13-21 years inclusive. Seventeen of the sites are Child and Adolescent Mental Health Services (CAMHS), 13 are Adult Services and eight of the sites have both CAMHS and Adult teams recruiting. All sites are managed within the NHS (public sector).

Participants
Patients newly referred to an ED outpatient service, with a primary diagnosis of AN according to DSM-IV criteria (American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV), 1994) or ED not otherwise specified AN type–EDNOS-AN), aged between 13 and 21, are offered the opportunity to participate in the research. In line with previous similar studies, age bounds are chosen to represent an adolescent sample, up until brain development comes to completion (early twenties) (Keverne, 2004). At least one carer living with the patient currently and for the next year, identified by the patient, must participate for the family to be included in the study, although all close carers are encouraged to take part. Carers are defined as someone who provides unpaid help and support to a parent, child, partner, relative, friend, or neighbour (The Princess Royal Trust for Carers., 2012). Patients receive different levels of support from carers but are, to varying degrees, dependent on the carer. Patients need to be able to provide consent and able to speak and understand English. Patients are excluded if they or their carers are taking part in another treatment study. In addition, participants with an identified severe comorbidity at time of admission (e.g. severe learning disability, psychosis) are excluded from the evaluation. No formal sample size calculation has been completed as this is a pilot RCT and will be used to obtain information on the likely effect size, variability and other aspects of outcome data. It may also be possible to estimate the experienced coaches’ intra-class correlation for a future definitive trial sample size calculation. We estimate that it is feasible to randomise 175 families over the planned 18-month recruitment phase.

Recruitment
Patients will be approached by clinical staff at the participating sites on initial assessment and given information about the study. Written and informed consent will be collected from all participants. Data on participant flow are collected according to Consolidated Standards of Reporting Trials recommendations (Moher et al., 2010). Clinical studies officers from the MHRN support recruitment of patients and administration of the study on eligible sites. Participants are entered into a prize draw for taking part in the study. They are not reimbursed or paid for participation.

Treatment arms
(1) Experienced carers helping others (ECHO)
Participants allocated to ECHO will receive the self-help version of the intervention. This is offered as an additional resource to treatment offered by clinical teams and is
not designed to replace any aspects of individual or family therapy. ECHO uses an educational and skills training approach and consists of self-help materials. Materials are posted to carers and includes a book co-authored by a professional, a carer and an individual with an ED (Treasure, Smith, & Crane, 2007), a series of video clips which illustrate the principles described in the book (e.g. using role plays and practical examples; see Sepulveda, Lopez, Macdonald and Treasure, 2008 for a more detailed description of DVD content), and a short guide for carers as a further supplement to the book. ECHO utilises several strategies that have been identified as important for the success of behaviour change interventions (Mitchie et al., 2011).

(2) Coaching with ECHO (ECHOc)

"Experienced coaches" are trained to deliver ECHOc.

In addition to the self-help materials, the ECHOc intervention package includes 10 telephone coaching sessions that will be allocated, where possible, between participating carers (e.g. mother and father). Participants will be contacted by the coach within two weeks of receiving the material by post. Coaches are asked to complete the sessions within a 5-month period. Calls can therefore be regular with a time lapse (e.g. 2 weeks) for carers to practise the skills. Calls are approximately 40 min in length, and carers receive a minimum of six calls (per family) to have completed the intervention.

Motivational Interviewing (MI) is the primary therapeutic tool used to deliver the telephone coaching (Rollnick, Butler, Knittersley, Gregory, & Marsh, 2010). The spirit of MI is empathic, deferential and curious, and coaches are trained to promote change through recognition of ambivalence in the individual, reflective listening and eliciting change talk, as detailed in Table 1. Coaches utilise behaviour change principles such as those outlined in the NICE guidelines (NICE, 2007) e.g. setting of action plans (considering goals and obstacles) for commitment to behaviour change. Carers are also taught MI skills to initiate change with the person for whom they are caring.

**INSERT TABLE 1 NEAR HERE**

*Telephone coaches*

The telephone coaches are individuals with personal or professional experience of ED. Of the 17 coaches, 10 have personal experience of AN or as a carer of someone with an ED. Inclusion criteria for coaches include that the carer coaches' loved ones are stable or in a maintenance phase of the illness. Those with an ED personal history must describe themselves as recovered for at least two years. The remaining seven coaches work in the field of EDs (researchers and clinicians). Eleven coaches were recruited from the earlier RCT 'Carer Assessment, Skills and Information Sharing' (CASIS) (see Goddard, et al., 2012) and the remaining coaches were recruited internally within the department. Coaches are offered payment for their time and running costs reimbursed.
Treatment fidelity and quality assurance (ECHOC)

All experienced coaches receive didactic training (eight face-to-face days) in MI and in the ECHO model based on the intervention book and DVDs. Experienced coaches are closely supervised with training cases (outside the study) and will only take on study participants when they have obtained a minimal level of competence as assessed by expert supervisors using the MITI 3.1.1 rating measures (Moyers, et al., 2010). The coaching sessions are audio-taped, and sessions 3 and 7 will be transcribed and coded using the MITI 3.1.1 for the purposes of supervision and treatment integrity and fidelity. In addition, coaches can contact the trainer/supervisor and other experienced coaches by phone or e-mail for further supervision. The level of background experience of the experienced coaches varies but the self-directed aspects of training allow for variable levels of practice and review.

The utilisation of ECHOC will be assessed using a self-report measure asking carers and coaches to rate the amount of the book read, DVDs watched and number of telephone sessions received. Coaches are also required to give a brief overview of each session in a session record form for each family. All coaches will be contacted simultaneously for each participant randomised, and families are allocated on a first-come-first-served basis. To limit potential bias we will share no information concerning participants with coaches prior to allocation.

Inclusion Criteria for carer coaches:

- People with experience of caring for people with AN (family or professional).
- People who have previously participated in skills based carer intervention.
- People with sufficient time for the training, supervision and coaching.
- Some training in professions allied to medicine, or equivalent (psychology, counselling) or teaching (not a requirement).
- Access to computers for the distance learning element as well as for email supervision and communication purposes.

Exclusion Criteria for carer coaches:

- Has a family member with AN who remains acutely ill.
- English not first language/fluent.

Assessment Measures:

2. The Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegen, 1988): This short-item scale asks participants to rate the degree to which they feel each of the validated moods. We have added ‘competent’ and ‘discouraged’ following discussion with the experienced carers. They will complete it twice per family (session 3 and session 7) before and after the session.

(3) TAU
The NICE guidelines have one grade B and several Grade C recommendations for the treatment of AN in adolescents and young adults (NICE, 2004). Accordingly, most people with AN should be managed on an outpatient basis with psychological treatment and physical monitoring provided by a health care professional competent to administer care and assess physical risk. NICE recommends this combination of treatment for at least six months’ duration, with more intensive forms of treatment to be considered in cases of significant deterioration, non-improvement or in cases of physical risk. Weight restoration in an outpatient setting should aim for an average weekly weight gain of 0.5kg and for adolescents, family interventions that directly address the ED should be offered (grade B). Furthermore, when treating adolescents, family involvement should be encouraged because of the effects of AN on other family members. Meanwhile, individual appointments (separate from family members or carers) should be made available to the patient.

The treatments delivered at each centre differ, e.g. the amount of contact time between patients and carers with professionals. The profile of each service is captured by the Client Service Receipt Inventory (detailed below). A variable describing the amount of direct carer-professional contact will be used as a covariate.

Those allocated to the TAU arm will be informed that they will have access to the intervention on completion of the study and given contact details for Beat, the leading UK ED charity.

**Outcome measures**

Participants (patients and carers) will complete assessments at baseline and over the course of one year by telephone interview and by self-report by post or email. These measures minimise participant burden and maximise engagement particularly for people with AN and in the TAU group who are not directly involved in ECHO. The assessments measure key outcomes and prognostic variables. Where interviews are completed, assessors are blind to treatment allocation.

Assessments for AN/EDNOS-AN subjects
1. Clinical and demographic information (baseline).
2. Short evaluation of ED (SEED) (Bauer, Winn, Schmidt, & Kordy, 2005). A brief, valid, reliable self-report measure to assess ED symptoms over the past week, scored by means of an algorithm including weight and key symptoms (baseline and monthly for 1 year).
3. The ED and Autistic Spectrum Sections of the (computerised version) Development and Wellbeing Assessment (DAWBA; www.dawba.com) (Goodman, Ford, Richards, Gatward, & Meltzer, 2000) are used. This is a validated semi-structured assessment completed by an informant (the primary caregiver/parent) and the individual themselves. Skip rules are used in the Autistic Spectrum Section so that the majority of participants do not have to complete all of the questions. The ED section of this interview was shown to be
reliable in detecting ED diagnoses in adolescents (House et al., 2008). Preliminary clinical diagnoses (according to DSM-IV, and ICD 10) are derived by an internal computer algorithm and an experienced clinical rater (NM) reviewed these taking into account open ended comments and assigned a final diagnoses (baseline, 1 year).

The Social Aptitude Scale (Liddle, Batty, & Goodman, 2009) is a ten item assessment instrument, completed by an informant, also as part of the DAWBA. It measures skills in social understanding and behaviour. A cut-off score of 16 (lower scores indicate poorer social aptitude) on the SAS is associated with sensitivity of 0.93 and specificity of 0.93 for the diagnosis of autism spectrum disorders. A modal score of 20 was found using data from a large epidemiologically based study of young people in the UK (http://www.dawba.com/SAS) (baseline, 1 year).

The Strengths and Difficulties Questionnaire is a well-validated 25-item screening questionnaire, completed by an informant and as self-report (patient), within the DAWBA. It is composed of five scales that assess behaviour problems, hyperactivity, emotional symptoms, peer problems and pro-social skills (Goodman, 2001). Scores for the first four subscales are added to form a total difficulties score. Ratings of child distress and the impact of difficulties on home life, friendships, classroom learning and leisure activities are combined to form a total impact score. The follow-up version assesses change in difficulties, using a five-point Likert-type scale (www.sdqinfo.com) (baseline, 1 year).

4. The Clinical Impairment Assessment 3.0 (CIA) (Bohn & Fairburn, 2008) is a 16-item scale to assess the overall impairment on psychosocial functioning as a result of the ED (baseline, 1 year).

5. The Depression, Stress and Anxiety Scale (DASS-21) (Lovibond & Lovibond, 1995) is a 21-item self-report measure of emotional symptoms (depression, anxiety, and stress) validated in both clinical and non-clinical samples with good internal reliability (baseline, 6-months, 1 year).


7. The Brief Dyadic Scale of Expressed Emotion Patient Version (Medina-Pradas et al, unpublished) is a 14-item scale to measure patients’ perspectives of levels of expressed emotion of their carers. Three subscales measure perceived criticism, perceived emotional involvement and perceived warmth. The scale is completed separately for each carer taking part in the project (baseline, 6 months).

8. The Treatment Satisfaction Questionnaire (Roots, Rowlands, & Gowers, 2009) is an established instrument rating prior expectation of, and motivation to, participate in treatment they have received (randomised or not) on a Likert Scale. The measure includes an area for free expression about any aspect of the services they have received (baseline, 6 months).
9. The Client Service Receipt Inventory (CSRI) is a well-established interview method of data collection, linked to cost analysis (Beecham & Knapp, 1999). A brief, version will be developed for this study, adapted for use with young people, to document each person's use of specialist and generic health services and education or employment (baseline, 6 months and 1 year).

Assessment for Carers
1. Clinical and demographic Information (baseline).
2. Depression, Stress and Anxiety Scale (DASS-21) (Lovibond & Lovibond, 1995) see above for details (baseline, 1 year).
3. General Health Questionnaire (GHQ-12) (Goldberg, 1972) is a well-validated 12-item measure assessing general wellbeing over the previous few weeks using a 4-point Likert scale (baseline, 1 year).
4. The Family Questionnaire (FQ) (Wiedemann, Rayki, Feinstein, & Hahlweg, 2002) is a 20-item self-report measure of expressed emotion in carers. Scores are given on a 4-point Likert scale and form two subscales: emotional over-involvement and criticism. Good internal consistency is reported for emotional over-involvement (0.78-0.80) and criticism (0.91-0.92) (baseline, 6 months).
5. The Accommodation and Enabling Scale for EDs (AESED) (Sepulveda, et al., 2009) is a 33-item self-report measure including five subscales: avoidance and modifying routine, reassurance seeking, meal ritual, control of family and turning a blind eye. Internal consistency for the scale is good (.77-.90 for subscales, .92 for total scale) (baseline, 6 months).
6. The Autism Quotient (AQ-10) (Allison, Auyeung, & Baron-Cohen, 2012) is a 10-item self-report version of the original AQ instrument measuring social skills, attention switching, attention to detail, communication, and imagination. Sensitivity was 0.93, specificity 0.95, and predictive value 0.86 at a cut-off point of 6 as indicative of ASD in adolescents (baseline).
7. The Obsessive Compulsive Inventory (OCI-R) (Foa, et al., 2002) is an 18-item self-report measure which assesses the frequency and associated distress of 6 obsessive compulsive symptom domains and a cut-off point of 21 indicative of obsessive compulsive disorder (baseline).
8. Family Meal Patterns (Neumark-Sztainer, Wall, Story, & Fulkerson, 2004) selected questions are included to assess attitudes to eating, weight or shape within the family and family eating patterns (baseline).
9. The Treatment Satisfaction Questionnaire (Roots, et al., 2009), as above (baseline, 6 months).
10. The Client Service Receipt Inventory (CSRI) (Beecham & Knapp, 1999), as above. Details also additional expenses for them or their family as a consequence of AN (baseline, 6 months and 1 year).

Primary outcomes
The primary outcome is rate of change of a summary symptom score measured at 6- and 12- month follow-up from the SEED. Weight data at assessment are obtained
from the outpatient team and thereafter via a monthly telephone interview (SEED) with patients. However, where patients are uncomfortable or unable to do this, consent to contact a professional who regularly records their weight will be obtained.

Secondary outcomes
Secondary outcomes include general psychiatric morbidity of AN and carer, carers’ coping and behaviour, change in health care use and costs at 6 months (end of treatment) and one year (follow-up), between groups (ECHOc, ECHO, and TAU). Difference between groups in change from baseline in:

- DAWBA diagnosis at one year
- CIA scores in AN at one year
- Health and social costs at six months and one year
- Depression, anxiety and stress in AN and carers measured at one year
- Expressed emotion (FQ) and accommodation and enabling behaviours (AESED) at six months. Change in these scores as mediators of outcome (both carer and patient)
- Carer and patient obsessive compulsive and autistic traits as moderators of outcome
- Familial eating patterns and attitudes as moderators of outcome

Process evaluation outcomes
Acceptability and Utility of ECHOc: This is a short form asking carers about their utilisation of ECHO, as well as visual analogue scales for acceptability. Carers and coaches will record how many telephone coaching sessions each carer received and the proportion of the book read and DVDs watched. Carers will be asked to rate their coach across different dimensions and the utility of the intervention for specific areas of interest (e.g. responses to the ED, communication and own stress levels). We will examine how quality impacts on outcome, in order to determine how quality should be assessed and controlled in the definitive trial.

Economic evaluation
Service Information Schedule (SIS): The SIS is used to record details of staff grade and time use, travel and other expenses, materials (book, DVDs and recording devices) as well as training and supervision provided to telephone coaches. These data allow estimation of the unit cost of the ECHO intervention. Staff costs will include salary overheads.

The CSRI (Beecham & Knapp, 1999) is a well-established resource-use schedule. It has been specifically adapted for this evaluation, to record patients’ and carers’ service use over the six months prior to each interview, distinguishing service use related to AN and for other reasons. Out-of-pocket expenses, social security benefit receipt and absences from work or education are also recorded, as is reduced work productivity and the impact of AN on their daily routine. The interview is conducted by telephone.
Observed confounding variables
The following variables will be entered into the statistical models as potential confounding variables:

- Demographic information (P, C): self-report gender, age, marital status, education level and employment status.
- ED history (C): a binary (yes/no) question about whether the carer has a history of difficulties with eating/shape/weight.
- Illness severity (P): duration of illness, lowest lifetime BMI, comorbidity and number of previous hospital admissions due to their ED. Current BMI and whether they use vomiting as a compensatory behaviour will also be included (randomisation stratification). All will be entered as separate possible confounders.
- Treatment (P): Centre of treatment will be coded.
- Readiness to change (P): Patients are asked to rate the importance of and confidence to change their ED on a Likert-type scale (0-10).
- Contact time (P, C): amount of face-to-face and other contact and whether carer and patient are living together.
- Carer involvement (P, C): the amount (frequency) carers are involved in treatment and the support they receive (e.g. carer support groups and family therapy).

Statistical analysis plan

Outcome analysis
All main analyses will follow the ‘intention to treat’ principle; that is, patients will be analysed in the groups to which they were randomised irrespective of treatments received.
A summary approach will be taken. Since this is a pilot, we do not anticipate having sufficient numbers to use repeated measures models. The time trend in AN symptoms as measured by SEED over 12 months for each person will be estimated using an appropriate method, and effect sizes calculated; for instance, a linear regression model if the trend is linear over time (we will explore other models if this is not the case). The parameter from these models that estimates the trend over time (i.e. the slope parameter) will be extracted for each person. The difference between the groups in the rate of change over time will then be examined by means of an Analysis of Variance (ANOVA) test applied to these summary parameter data. Tukey’s correction will be used to adjust for multiple statistical tests.

Economic evaluation
The number of contacts with health care services will be compared. In addition, a unit cost for each service will be estimated using a compendium of nationally applicable data (Curtis & Netten, 2008) or using an equivalent methodology, including for the interventions. Costs per case will be calculated as the unit cost
multiplied by the use made of each service over the three months prior to interview with repeat measures at 6- and 12- months. Costs of ECHOc will also be made: training, supervision, and number/duration of contacts to each carer.

Discussion

The aim of this pilot trial is to investigate the use of the ECHO intervention (guided, not guided) for adolescents with AN or EDNOS-AN at an early stage of illness referred for outpatient care. The intervention is based upon an interpersonal maintenance model of EDs (Schmidt & Treasure, 2006; Treasure & Schmidt, 2013) and represents the next step in a series of experimental studies developing ECHO. This study will be the first to investigate the use of guided skills training for carers of adolescent sufferers, most of whom are at the early intervention stage (i.e. initial stage of the illness), by using quantitative measures for both patient and carer outcomes. The design of this intervention is novel as the needs of family members themselves have not been taken into account in the field, despite the high levels of dependency and disability associated with AN.

Limitations and challenges

First, the necessity to involve both patients and carers may have a negative effect on the accrual rate. However, this is a novel aspect of the study as the well-being and costs of care by parents of adolescents with AN has not been considered previously. We anticipate the assessment procedure will seem burdensome at times, and we will accommodate participants’ needs where possible (e.g. alternative reliable correspondence for weight data). We anticipate that the families who are allocated to TAU may be disappointed and may not adhere to follow-up. We will strive to minimise this by offering carers the intervention materials on completion of the project and by sending regular newsletters and personalised reminders, birthday greetings, etc. An additional difficulty with the design of the trial is the heterogeneity in treatment provision across treatment centres and individuals and families will vary in their level of engagement in treatment programmes. This heterogeneity is acknowledged in the use of pragmatic trial design and a randomised procedure that stratifies by treatment centre. The level of motivation, receipt of individual treatment and family involvement in treatment can be included in the analysis.

Training and support for telephone coaches is another challenge as coaches are themselves volunteers and cannot commit to the level of training and supervision that other professionals may receive. In addition to the supervision offered in different formats (e.g. telephone, email and face-to-face) and quality control we will share new developments through the web site developed by P.M. www.thenewmaudsleyapproach.co.uk. We will also provide annual conferences for carers (with special sessions for the carer coaches) to enable them to meet the team face-to-face and to also place their participation in the research into the larger context of research and development in this area. The carer coaches will also be invited to more specific training held at SLAM for professionals. Members of the
research team will also accept invitations to talk about the study at the local recruitment sites.

Conclusion
In sum, this paper outlines the protocol for a project that will add to the small literature base on interventions for AN and EDNOS-AN, focusing on adolescents at the early stage of illness. We have outlined the components of the ECHO intervention and clearly stated the research methodology in accordance with recommendations that will improve reporting and replication of treatment evaluations (Glasziou, Meats, Heneghan, & Shepperd, 2008; Moher, et al., 2010). We hope that the findings from this study will determine the parameters for, and be used to execute, a definitive trial. and pave the way for more integrated and collaborative interventions that have the potential to improve outcome in AN and EDNOS-AN at a small cost to services.

List of Abbreviations

ED, Eating Disorders; AN, Anorexia Nervosa; EDNOS-AN, Eating Disorder Not Otherwise Specified, Anorexia Nervosa Subtype; ECHO, Experienced Coaches Helping Others; CASIS, Carers Assessment, Skills and Information Sharing; RCT, Randomized Controlled Trial; NICE, National Institute for Health and Clinical Excellence; MI, Motivational Interviewing.

Competing interests

JT is an author of the book used in the ECHO intervention (Treasure et al., 2007). RH, CR, EG, PM and GT provided coaching in the ECHOc treatment arm.

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Figures and Tables

Figure 1.

Clinician assessment

Baseline assessment by researcher or CSO

Excluded

Randomisation

ECHO

Monthly SEEDs

6 months follow-up assessment

Monthly SEEDs

12 months follow-up assessment & qualitative feedback

ECHOc

Monthly SEEDs

6 months follow-up assessment

Monthly SEEDs

12 months follow-up assessment & qualitative feedback

TAU

Monthly SEEDs

6 months follow-up assessment

Monthly SEEDs

12 months follow-up assessment & qualitative feedback

Offer ECHO intervention

Figure 1. Study design
Table 1: Description of carer maintaining factors targeted by the intervention.

<table>
<thead>
<tr>
<th>Maintaining Factors and how they are Targeted in the Carer skills Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety, depression</td>
</tr>
<tr>
<td>Guilt and shame</td>
</tr>
<tr>
<td>Rigidity, compulsivity, preoccupation with detail, eating</td>
</tr>
<tr>
<td>Misperceptions and misunderstanding of eating disorders</td>
</tr>
<tr>
<td>Enabling and accommodating to the illness</td>
</tr>
<tr>
<td>Expressed emotion (criticism, hostility and overprotection)</td>
</tr>
<tr>
<td>Unhelpful communication</td>
</tr>
</tbody>
</table>
References


Hibbs (2014b, in preparation). A randomised controlled trial to evaluate the efficacy of adding a guided self help intervention (ECHO) for carers of inpatients with Anorexia Nervosa (CASIS).


