

A multicentre pilot study testing Expert Carers Helping Others: a self-help skills training intervention for carers of someone with anorexia nervosa

Submission date

29/09/2011

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

29/09/2011

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

05/10/2018

Condition category

Mental and Behavioural Disorders

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9417

Study information

Scientific Title

Does a proven intervention to improve functioning of carers also benefit the anorexia nervosa sufferer for whom they care? A pilot study of our Expert Carer Helping Others (ECHO) intervention

Acronym

ECHO

Study objectives

We aim to find out if ECHO results in more rapid and stable reduction in AN symptoms of patients aged 13-21 compared to treatment as usual (TAU) alone by providing carers with information and effective skills. In a third arm we will find if the addition of coaching (ECHOc) from 'expert carers' i.e. individuals with their own experience of living with an ED, makes a difference.

Secondary research questions are:

1. What are the relative costs between arms?
2. What are the effects on carers wellbeing between arms?
3. Do reductions in maintaining variables mediate outcome for patients?
4. Do obsessivecompulsive disorder (OCD) traits in individual and parents (autistic, OCD) have a moderate effect on ECHO on carer and patient outcome?
5. Does parental attitudes and behaviour to food and weight/shape moderate carer and patient outcome?
6. Can ECHOc be delivered to a high level of competence?
7. Are there therapist effects?

Ethics approval required

Old ethics approval format

Ethics approval(s)

First MREC, 21/03/2011, ref: 11/H0724/4

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Anorexia Nervosa and Eating Disorder Not Otherwise Specified (Anorexic subtype)

Interventions

Expert Carers Helping Others: a self-help, skills training intervention for carers of someone with an eating disorder. Intervention materials (book, DVDs, accompanying manual) are posted to carers. Those who are in the guided self-help arm receive 10 telephone coaching sessions delivered by a trained 'Expert Coach'. This coach has previous experience of eating disorders, either having recovered themselves or having cared for someone affected. Only carers receive the intervention and it can be shared between carers (e.g. mother and father). The intervention is additional to what the family would be offered as part of their clinical treatment. Treatment as usual refers to the standard treatment offered as part of the clinical package and should not change as a result of the project.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Summary score of core eating disorder symptoms of patients collected using the Short Evaluation of Eating Disorders Symptom (SEED)

Secondary outcome measures

1. Carers' wellbeing (General Health Questionnaire) and distress (Depression, Anxiety and Stress Scale) (baseline, 6 months, 12 months follow-up)
2. Expressed emotion (Family Questionnaire - carer response; Brief Dyadic Scale of Expressed Emotion - patient response; baseline, 6 months)
3. Accommodating and enabling behaviours (Accommodating and Enabling for Eating Disorders; carer response baseline, 6 months)
4. Caregiving self efficacy (carer and patient response; baseline and 6 months)
5. Patient diagnostic category (Development and Well-Being Assessment; baseline, 12 months)
6. Patient distress (Depression, Anxiety and Stress Scale; baseline, 6 months, 12 months)
7. Health economic assessment for carers and patient (Client Service Receipt Inventory; baseline, 6 months, 12 months)

Overall study start date

10/06/2011

Completion date

10/12/2012

Eligibility

Key inclusion criteria

1. Person with anorexia nervosa (AN) or eating disorder not otherwise specified - anorexia nervosa (EDNOS-AN) type referred to outpatient clinic for their eating disorder
2. Patient aged 13-21 years old
3. Carers living with someone diagnosed with AN or EDNOS-AN currently and for the next year at minimum outside of term time
4. Person with AN and carers (at least one) consent
5. New referral to outpatient eating disorder service

Participant type(s)

Patient

Age group

Child

Lower age limit

13 Years

Upper age limit

21 Years

Sex

Both

Target number of participants

Planned Sample Size: 350; UK Sample Size: 350; Description: 175 patients will be recruited (accounting for drop out) and at least one carer

Key exclusion criteria

1. Either patient or carer has insufficient knowledge of English
2. AN comorbid with severe psychiatric or physical comorbidity e.g. learning disability, psychotic illness (including bipolar disorder), alcohol/drug abuse, metabolic or gastrointestinal problems (diabetes mellitus, celiac disease) (not including mood disorder, OCD, BDD, ASD)
3. Family in a concurrent treatment trial

Date of first enrolment

10/06/2011

Date of final enrolment

10/12/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

South London and Maudsley NHS Trust (UK)

Sponsor details

Michael Rutter Centre for Children
Maudsley Hospital
De Crespigny Park
London
England
United Kingdom
SE5 8AZ
+44 (0)20 3228 6000
a@b.com

Sponsor type

Hospital/treatment centre

Website

<http://www.slam.nhs.uk/>

ROR

<https://ror.org/015803449>

Funder(s)

Funder type

Government

Funder Name

NIHR (UK) ref: PB-PG-0609-19025

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/07/2014		Yes	No
Results article	results	20/12/2014		Yes	No
Results article	results	01/07/2016		Yes	No
Results article	results	01/11/2017		Yes	No