

# A patient and carer shared management intervention for anorexia

<b>Submission date</b> 06/12/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 08/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2026	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Anorexia nervosa (AN) is a serious eating disorder in which people keep their body weight low by dieting, vomiting, using laxatives or excessively exercising. It affects men and women of all ages, but is most common in young women. AN affects the whole body, and can lead to serious mental health issues, such as depression and problems with cognitive (thinking, learning and memory), as well as damage to major organs such as the heart and kidneys. If the weight loss is particularly severe, then hospitalizing the sufferer to help them gain weight is the main treatment option. The length of hospital stay and death rate in the year after admission for patients with severe anorexia nervosa is higher than for other psychiatric conditions. It has been found that that actively involving the family in shared management reduces the readmission rate and improves both patient and family well-being. It has also been found that self-management materials for patients also improves outcomes. The aim of this study is examine whether adding self-management materials for both carers and patients improves both patient and carer outcomes and service use in the year following specialist inpatient treatment for patients with severe anorexia nervosa.

### Who can participate?

Anorexia patients aged 17 or over who have a carer including family and/or friends willing and able to provide some aftercare support) who is also willing to take part

### What does the study involve?

Patients and their carers are randomly allocated to one of two groups. Those in the first group receive usual treatment alone. Those in the second group receive usual treatment with the addition of the shared self-management materials, which are available online. The self-management materials are available on two online platforms (one for patients and one for carers) and contain self-management tools which support the individual and the family, such as workbooks, DVD, vodcasts, questionnaires, feedback, with chat line and e mail support. Patients' and carers' wellbeing are measured on admission and at 3-monthly intervals over the following 18 months using multi-method assessment techniques. In addition, service use, costs, and the role of prospective mediators and moderators of clinical outcomes are measured.

What are the possible benefits and risks of participating?

Findings from previous scientific studies show that both parties (carers and patients) can benefit from this type of program. Carers experience less stress and burden, and patients maintain the changes from inpatient care more effectively. There are no notable risks involved with participating.

Where is the study run from?

22 NHS or non-NHS inpatient/daycare units in England and Scotland (UK)

When is the study starting and how long is it expected to run for?

November 2016 to October 2021

Who is funding the study?

National Institute for Health Research - Health Technology Assessment Programme (UK)

Who is the main contact?

Dr Valentina Cardi

valentina.cardi@kcl.ac.uk

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Valentina Cardi

**ORCID ID**

<https://orcid.org/0000-0002-7763-7099>

**Contact details**

King's College London

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London

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valentina.cardi@kcl.ac.uk

## Additional identifiers

**Protocol serial number**

197114

## Study information

**Scientific Title**

A multicentre, investigator-blinded, randomised, 18 month, parallel group, superiority study to examine whether the addition of a patient and carer shared management intervention improves patient wellbeing following inpatient treatment for anorexia nervosa

## **Acronym**

TRIANGLE

### **Study objectives**

The overall aim is to compare the effectiveness and cost-effectiveness of adding a shared management intervention aimed at reducing patients' distress to treatment as usual for inpatients with anorexia nervosa. Using a randomized controlled trial, we will examine whether there is an improvement in eating disorder symptoms with less care-giving burden and service use in the 18 months post-admission.

#### **Primary objective:**

To examine whether adding a guided shared management intervention for patients and carers aimed at reducing patients' distress is more effective than usual care in the 18 months following admission.

#### **Secondary objectives:**

1. To assess the following secondary hypotheses as to whether augmenting aftercare treatment as usual with a combined skills-sharing intervention will:
  - 1.1. Improve BMI and increase quality of life for patients in the year following admission
  - 1.2. Reduce distress, burden and increase quality of life for carers in the year following admission
  - 1.3. Reduce days in hospital in the 18 months post-discharge
  - 1.4. Be more cost-effective than treatment as usual in terms of distress and quality-adjusted life years gained in the 18 months following admission
2. To have available a set of theoretically-grounded, empirically-supported tools including highly-teachable health behaviour techniques for patients, carers, and professionals that can be readily disseminated
3. To examine the process variables that are thought to mediate and moderate change for patients and caregivers
  - 3.1. To determine the impact of the combined intervention on variables targeted by the various component parts of the intervention (e.g. accommodation, expressed emotion, interpersonal functioning)
  - 3.2. To assess the fidelity of the intervention using (1) rating scales, (2) thematic analysis of guidance sessions (3) feedback (qualitative and quantitative) from patients and caregivers
  - 3.3. To conduct exploratory analyses of whether BMI, level of psychopathology, duration of illness, type of admission (voluntary/involuntary) has an impact on overall outcome and whether there is an interaction with type of aftercare given

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee London - Camberwell and St Giles, 07/10/2016, ref: 16/LO/1377

### **Study design**

Multi-centre randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

## Treatment

### Health condition(s) or problem(s) studied

Anorexia nervosa

### Interventions

Participants are randomised to one of two groups by King's Clinical Trials Unit based on patient body mass index and clinical service.

**Intervention arm:** Participants and their carers will be able to access the intervention materials on the study website. The intervention materials consist of: a workbook, a library of short video-clips; 8 online group forum sessions and up to 6 joint Skype sessions (patient-carer) with a health professional. Participants will be able to use the workbook and video-clips and to take part in 4 online group forums during hospital admission. At discharge, they will be able to participate in 4 additional online group forums and will be able to receive up to 6 joint Skype sessions with a health professional. Participants will complete regular assessments up to 18 months post-randomisation (i.e. baseline; monthly surveys; questionnaires at 3, 6, 9, 12 and 18 months). Participants will receive a visual feedback of their scores over time, after completing some of these questionnaires. The questionnaires will be completed on the study website.

**Control arm:** Participants and their carers will be randomised by the King's Clinical Trials Unit based on patient body mass index and clinical service. Those allocated to the control condition will complete regular assessments on the study website (i.e. baseline questionnaires; weekly surveys; questionnaires 3-, 6-, 9-, 12-, and 18-month post-randomisation). Participants will receive a visual feedback of their scores over time, after completing some of these questionnaires.

### Intervention Type

Behavioural

### Primary outcome(s)

Patients' psychological wellbeing is measured using the Depression, Anxiety and Stress Scales questionnaire at baseline and 12 months post-randomisation

### Key secondary outcome(s)

1. Weight and height is obtained at baseline and from monthly clinical measurements at each centre, up to 18 months post-randomisation. Patient's weight is also self-reported at baseline and on a monthly basis, up to 18 months post-randomisation
2. Patients' psychological wellbeing measured using the Depression, Anxiety and Stress Scales questionnaire at baseline and 18 months
3. Eating disorder psychopathology is measured using the Eating Disorder Examination-Questionnaire at baseline, 12 and 18 months
4. Quality of life is measured using the EQ-5D questionnaire at baseline and 12 months
5. Importance and confidence to change is measured using visual analogue scales at baseline and 12 and 18 months
6. Social functioning is measured through the Strengths and Difficulties Questionnaire completed by carers at baseline and 12 months
7. Work and social adjustment is measured using the Work and Social Adjustment Scale at baseline and 12 and 18 months
8. Intervention cost-effectiveness is measured using the Client Service Receipt Inventory at baseline and 12 months

9. Service use/readmission rates are measured using Hospital Episode Statistics at baseline and 12 and 18 months

Carer outcomes:

1. Psychological wellbeing is measured using the Depression, Anxiety and Stress Scales questionnaire at baseline and 12 and 18 months
2. Skills to cope with eating disorder behaviours is measured using the Caregiver Skills (CASK) scale at baseline and 12 and 18 months

**Completion date**

31/10/2021

## Eligibility

### Key inclusion criteria

Inclusion criteria as of 07/06/2017:

1. Aged 17 years or over
2. With a DSM-5 diagnosis of Anorexia Nervosa or atypical/subclinical Anorexia Nervosa and a body mass index (BMI) of  $< 18.5 \text{ kg/m}^2$
3. With a carer willing to participate. A broad definition of "carer" will be used to include family and/or friends willing and able to provide some aftercare support
4. Consent form signed within 2 months from admission
5. Participants able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and the internet in order to use the study's website)

Original inclusion criteria:

1. Consecutive admissions for in/day patient care
2. Aged 17 years or over
3. DSM-5 diagnosis of Anorexia Nervosa with a body mass index (BMI) of  $< 18.5 \text{ kg/m}^2$
4. With a carer willing to participate. We will use a broad definition of "carer" to include family and/or friends willing and able to provide some aftercare support
5. Informed consent signed within 1 month from admission
5. Participants able to access an electronic device (e.g. mobile phone, computer, laptop, tablet) and the internet in order to use the study's website

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Mixed

### Lower age limit

18 years

### Upper age limit

100 years

### Sex

All

### **Total final enrolment**

371

### **Key exclusion criteria**

Exclusion criteria as of 07/06/2017:

1. The patient is not admitted for inpatient care or is not attending daycare for a minimum of 4 days/week at the time of consenting
2. The patient has an insufficient knowledge of English
3. The patient has severe mental or chronic physical illness needing treatment in its own right (e.g. psychosis, diabetes mellitus, cystic fibrosis etc)
4. The patient is pregnant
5. The patient-carer dyad has previously received treatments involving the ECHOMANTRA materials (e.g. as part of iMANTRA trial or CASIS study)

Original exclusion criteria:

1. The patient has an insufficient knowledge of English
2. The patient has severe mental or chronic physical illness needing treatment in its own right (e.g. psychosis, diabetes mellitus, cystic fibrosis etc)
3. The patient is pregnant
4. The dyad has previously received treatments involving the ECHOMANTRA materials (e.g. as part of the iMANTRA trial or the CASIS study)

### **Date of first enrolment**

20/06/2017

### **Date of final enrolment**

30/06/2020

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Scotland

### **Study participating centre**

**Bethlem Royal Hospital**

Monks Orchard Road

Beckenham

England

BR3 3BX

### **Study participating centre**

**Bowmere Hospital**

The Countess Of Chester Health Park  
Liverpool Road  
Chester  
England  
CH2 1BQ

**Study participating centre****Kinver Centre (In-patient Unit) St Chads House**

St Georges Hospital  
Corporation Street  
Stafford  
England  
ST16 3AG

**Study participating centre****Aspen Centre**

Lakin Road  
Warwick  
England  
CV34 5BW

**Study participating centre****Southmead Hospital**

STEPS Eating Disorder Services  
Clifton Building  
Bristol  
England  
BS10 5NB

**Study participating centre****St Ann's Hospital**

Eating Disorders Service  
Kimmeridge Court  
69 Haven Road  
Canford Cliffs  
Poole  
England  
BH13 7LN

**Study participating centre**

**Eating Disorders Service**

Kent and Medway NHS and Social Care Partnership Trust  
22 Oakapple Lane  
Maidstone  
England  
ME16 9NW

**Study participating centre****Vincent Square Eating Disorder Service**

Central and North West London NHS Foundation Trust  
1 Nightingale Place  
London  
England  
SW10 9NG

**Study participating centre****St Ann's Hospital**

The Phoenix Wing St Ann's Eating Disorders Service  
ST Ann's Road  
Tottenham  
London  
England  
N15 3TH

**Study participating centre****Leicestershire Adult Eating Disorders Service**

The Bennion Centre, Langley Ward  
Glenfield Hospital  
Groby Road  
Leicester  
England  
LE3 9DZ

**Study participating centre****Rharian Fields**

The Gardens  
Second Avenue  
Grimsby  
England  
DN33 1NU



**Study participating centre**  
**Regional Eating Disorder Service**  
Richardson Unit,  
Leazes Wing,  
Royal Victoria Infirmary  
Newcastle upon Tyne  
England  
NE1 4LP

**Study participating centre**  
**Inpatient Unit for the North of Scotland**  
The Eden Unit  
Block C, Clerkseat Building  
Royal Cornhill Hospital  
Cornhill Road  
Aberdeen  
Scotland  
AB25 2ZH

**Study participating centre**  
**St John's Hospital**  
South East Scotland Regional Eating Disorders Unit  
Howden Road West  
Howden  
Livingston  
Scotland  
EH54 6PP

**Study participating centre**  
**Springfield University Hospital**  
Avalon Ward  
Springfield University Hospital Building 61  
61 Glenburnie Road  
London  
England  
SW17 7DJ

**Study participating centre**  
**Addenbrooke's Hospital**  
S3 in-patient ward  
Hills Road

Cambridge  
England  
CB2 2QQ

**Study participating centre**

**The Barberry**  
25, Vincent Drive  
Edgbaston  
Birmingham  
England  
B15 2FG

## Sponsor information

**Organisation**

South London and Maudsley NHS Foundation Trust

**ROR**

<https://ror.org/015803449>

**Organisation**

King's College London

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute for Health Research - Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

Location  
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Janet Treasure (janet.treasure@kcl.ac.uk)

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		27/05/2024	20/01/2025	Yes	No
<a href="#">Results article</a>		18/07/2025	22/07/2025	Yes	No
<a href="#">Protocol article</a>		01/11/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	Qualitative investigation	20/07/2022	19/01/2023	Yes	No
<a href="#">Other publications</a>	Qualitative study of patient and carer experiences of a hybrid online guided self-help intervention (ECHOMANTRA)	16/04/2024	17/04/2024	Yes	No
<a href="#">Other publications</a>	Perceived carer skills and psychological distress	25/12/2025	06/01/2026	Yes	No