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A patient and carer shared management intervention for anorexia

Submission date
06/12/2016

Recruitment status
No longer recruiting

Registration date
08/12/2016

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 Insitute 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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

Secondary outcome measures

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

Overall study start date
01/11/2016

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 kg/m2
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 kg/m2
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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
380

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
England

Scotland

United Kingdom

Study participating centre
Bethlem Royal Hospital
Monks Orchard Road
Beckenham
United Kingdom
BR3 3BX

Study participating centre
Bowmere Hospital
The Countess Of Chester Health Park
Liverpool Road
Chester
United Kingdom
CH2 1BQ

Study participating centre
Kinver Centre (In-patient Unit) St Chads House
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3AG

Study participating centre
Aspen Centre
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Southmead Hospital
STEPS Eating Disorder Services
Clifton Building
Bristol
United Kingdom
BS10 5NB

Study participating centre
St Ann's Hospital
Eating Disorders Service
Kimmeridge Court
69 Haven Road
Canford Cliffs
Poole
United Kingdom
BH13 7LN

Study participating centre
Eating Disorders Service
Kent and Medway NHS and Social Care Partnership Trust
22 Oakapple Lane
Maidstone
United Kingdom
ME16 9NW

Study participating centre
Vincent Square Eating Disorder Service
Central and North West London NHS Foundation Trust
1 Nightingale Place
London
United Kingdom
SW10 9NG

Study participating centre
St Ann's Hospital
The Phoenix Wing St Ann's Eating Disorders Service
ST Ann's Road
Tottenham
London
United Kingdom
N15 3TH

Study participating centre
Leicestershire Adult Eating Disorders Service
The Bennion Centre, Langley Ward
Glenfield Hospital
Groby Road
Leicester

United Kingdom
LE3 9DZ

Study participating centre
Rharian Fields
The Gardens
Second Avenue
Grimsby
United Kingdom
DN33 1NU

Study participating centre
Regional Eating Disorder Service
Richardson Unit,
Leazes Wing,
Royal Victoria Infirmary
Newcastle upon Tyne
United Kingdom
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
United Kingdom
AB25 2ZH

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

Study participating centre

Springfield University Hospital
Avalon Ward
Springfield University Hospital Building 61
61 Glenburnie Road
London
United Kingdom
SW17 7DJ

Study participating centre
Addenbrooke's Hospital
S3 in-patient ward
Hills Road
Cambridge
United Kingdom
CB2 2QQ

Study participating centre
The Barberry
25, Vincent Drive
Edgbaston
Birmingham
United Kingdom
B15 2FG

Sponsor information

Organisation
South London and Maudsley NHS Foundation Trust

Sponsor details
Maudsley Hospital
Denmark Hill
London
England
United Kingdom
SE5 8AZ
+44 (0)20 3228 6000
jennifer.liebscher@kcl.ac.uk

Sponsor type
Hospital/treatment centre

Website

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

ROR
https://ror.org/015803449

Organisation
King's College London

Sponsor details
Strand
London
England
United Kingdom
WC2R 2LS
+44 (0)20 7836 5454
keith.brennan@kcl.ac.uk

Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
National Insitute for Health Research - Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The overall aim is to inform clinical practice within the NHS. Given that a large proportion of the intervention includes materials that are in production with a minimal amount of guidance, we anticipate that the intervention is scalable with the possibility for high reach. Indeed, past research suggests that interventions requiring limited professional input may be more readily disseminated (69). The dissemination plan will target various audiences at different levels:
1. Professional: Planned submission of papers including the study protocol to leading journals. Authorship will determined based on the contribution to each paper. Planned presentation of findings at eating disorder, psychiatric, student counselling and primary care conferences etc. We will disseminate the results to the special interest groups within the professional bodies of the multiple disciplines involved in the care of this group of patients (nurses, psychology, occupational therapy, dieticians, social workers, etc.). Data sharing with potential collaborators (UK and International) will be encouraged.
2. Policy: A full report with the executive summary will be sent to all NHS commissioning agencies. The co-applicant LG, COO of BEAT, will use this to assist in dialogues with policy makers, including MPs.
3. Patients and public: BEAT will coordinate this aspect of dissemination. Dissemination strategies will include presentations/blogs on eating disorder charities and carer and user websites and communication channels (FEAST, BEAT, Students Mind, etc.) at yearly carers' and users' workshops, media articles, discussion forums, website postings, and schools' training events. Training will be conducted through presentations, discussions, small groups teaching and large group seminars. A summary of findings will be made available on the websites of the key charities and the Psychological Medicine website at the Institute of Psychiatry. All participants will also be sent newsletters and will have free admission to the carers conference.
4. Media: The Press Offices at South London and Kings College will co-ordinate dissemination to the media. The study team aims to present the results on radio Woman's Hour and All in the Mind. Patient participation groups, newspapers and neighbourhood organizations will also be contacted to disseminate findings.

Intention to publish date
01/11/2022

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?
Protocol article		01/11/2017		Yes	No
Other publications	Qualitative investigation	20/07/2022	19/01/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study of patient and carer experiences of a hybrid online guided self-help intervention (ECHOMANTRA)	16/04/2024	17/04/2024	Yes	No
Results article		27/05/2024	20/01/2025	Yes	No

Results article	18/07/2025	22/07/2025	Yes	No