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A randomised pragmatic trial comparing the cost effectiveness of supplementing standard care with an intervention for carers (Carers Assessment, Skills and Information Sharing [CASIS]) of people with eating disorders

Submission date
19/08/2008

Recruitment status
No longer recruiting

Registration date
07/11/2008

Overall study status
Completed

Last Edited
12/09/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Eating disorders are serious psychiatric illnesses characterised by an abnormal attitude towards food that causes someone to change their eating habits and behaviour. Quality of life is also severely impaired in the family members of those affected, as these people often act as their main carers. The aim of this study is to help the carers of people with eating disorders in order to reduce their distress. It uses a self-management intervention for carers supplemented by coaching from experienced carers who have been trained in caregiving skills.

Who can participate?
Eating disorder inpatients aged 13 or older and their carers

What does the study involve?
Carers are randomly allocated to receive either the guided self-help intervention (in addition to treatment as usual) or treatment as usual only. Treatment takes about 3 - 6 months, and follow-up continues for one year. The outcomes measured are health and quality of life for carers and the person they care for at the end of inpatient treatment and for the following two years.

What are the possible benefits and risks of participating?
The information from this study may help to provide better services and treatment for future patients with an eating disorder.

Where is the study run from?
15 specialised eating disorder centres in the UK

When is the study starting and how long is it expected to run for?
August 2008 to February 2012

Who is funding the study?
1. National Institute for Health Research (NIHR) (UK)
2. South London and Maudsley NHS Foundation Trust (UK)

Who is the main contact?
Prof. Janet Treasure

Contact information

Type(s)
Scientific

Contact name
Prof Janet Treasure

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Study information

Scientific Title
A randomised pragmatic trial comparing the cost effectiveness of supplementing standard care with an intervention for carers (Carers Assessment, Skills and Information Sharing [CASIS]) of people with eating disorders

Acronym
CASIS

Study objectives
Eating Disorders are serious psychiatric illnesses. Life-time prevalence rates for anorexia nervosa are at minimum 1.6% in women and 0.3% in men. It is a life-threatening illness with the highest mortality rate of any functional psychiatric disorder. Educational, vocational and social functioning is commonly impaired in people who have an eating disorder. Quality of life is severely impaired in family members of someone affected as these people are often the main carers of their loved one with an eating disorder.

Eating disorders are also one of the most costly psychiatric conditions to treat, mainly due to the need for prolonged and/or repeated hospital admissions. Twenty seven percent of stays over 90 days in specialist inpatient units are due to eating disorders. Eating disorders are the most common diagnostic group in adolescent beds. Therefore, the cost of eating disorders to the individual, the family and society are high.

Hypothesis:
1. Patients whose carers receive the skills training intervention materials will have a lower relapse rate than those whose carers do not receive the materials after discharge from inpatient care
2. Depression and anxiety in carers who receive the materials will be lower than those who do not receive the materials over time
3. Providing carers with skills training intervention will decrease the cost of illness to the affected individual, carers and society in terms of reducing the number of inpatient days and a reduction in costs to the family (health care, out-of-pocket expenses and lost productivity) compared to those who do not receive the skills training intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Office at Royal Free Hospital, 15/05/2008, ref: 08/H0720/41

Study design
Longitudinal multicentre pragmatic randomised controlled intervention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Randomisation will be conducted independently from the trial team by the Clinical Trials Unit (CTU).

Intervention arm:
5 x skills training DVDs and 1 x skills training for carers of someone with an eating disorder developed by Professor Treasure and colleagues using a carers distress model and the techniques of motivational interviewing to teach communication strategies specifically for someone with an eating disorder. These materials will be accompanied by telephone coaching provided by "expert carers" or coaches trained in the model and in motivational interviewing techniques. Carers will receive 3 x half hour telephone coaching sessions.

Control arm:
Inpatient treatment as usual.

Treatment will occur for about 3 - 6 months, and follow-up will take place for one year.

Intervention Type
Other

Phase

Not Specified

Primary outcome(s)
1. Patient - time to relapse:
1.1. Body mass index (BMI) below 17.5 kg/m^2 for patients who were fully weight recovered at the time of discharge, measured at monthly intervals, or
1.2. A drop in 1 BMI point (approx 3 kg) for those who entered the study at a below normal weight and absolute weight, measured at monthly intervals
2. Carers - distress: Depression, Anxiety and Stress Scale (DASS), measured at patient discharge, 6 months, and 12 months follow up
3. Cost: Client Service Receipt Interview (carer and patient version), measured at baseline, discharge, 6 and 12 month follow up; except not at discharge for patient

Key secondary outcome(s))
1. Patients (all measured at baseline, discharge, 6 month and 12 month follow up):
1.1. Eating pathology: Eating Disorder Questionnaire (EDE-Q)
1.2. Distress: DASS
1.3. Quality of Life: World Health Organisation Quality of Life Questionnaire (WHOQuol)
2. Carers (all measured at baseline, discharge, 6 month and 12 month follow up except ECI which will not be measured at discharge):
2.1. Care giving burden: Experience of Caregiving Inventory, Eating Disorder
2.2. Symptom Impact Scale
2.3. Expressed emotion: Family Questionnaire, Levels of Expressed Emotion (patient perspective)
2.4. Quality of Life: WHOQuol

Completion date
20/02/2012

Eligibility

Key inclusion criteria
1. Patients:
1.1. Diagnosis of an eating disorder
1.2. 13 years or older, either sex
1.3. Current inpatient
1.4. Has a carer
2. Carer:
2.1. Cares for someone with an eating disorder
2.2. English speaking

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex

All

Key exclusion criteria
1. Patients:
1.1. Not currently admitted to an inpatient unit
1.2. No diagnosis of Eating Disorder
1.3. 12 years old or younger
2. Carer:
2.1. Does not speak English

Date of first enrolment
20/08/2008

Date of final enrolment
20/02/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Institute of Psychiatry, King's College London (UK)

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (ref: TW11 0XX)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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?
Results article	results	20/08/2015		Yes	No
Results article	results	01/08/2017		Yes	No
Protocol article	protocol	01/01/2013		Yes	No