Collaborative Caring Project: Working with Parents at treatment and secondary prevention of Eating Disorders

Submission date	Recruitment status	Prospectively registered
04/10/2005	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/06/2006	Completed	[X] Results
Last Edited	Condition category	☐ Individual participant data
28/10/2016	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 238/04

Study information

Scientific Title

Collaborative Caring Project: Working with Parents at treatment and secondary prevention of Eating Disorders

Acronym

CCP: WP_ED

Study objectives

Aim: to test the efficacy and acceptability in a preliminary randomised controlled trial (RCT) of skills training workshops for carers

Hypothesis 1: the carers workshops reduce the level of difficulties and distress involved in caring for someone with an eating disorder

Hypothesis 2: if the carers reduce their distress, this improves the outcome in people with eating disorders (ED)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by Multicentre Ethics Research Committee, reference number: 238/04 / MREC N.:04 /Q0706/132

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Having a relative with an eating disorder

Interventions

Design: the primary caregiver will be randomised to either:

- 1. Immediate workshop
- 2. Waiting list

Randomisation schedules will be generated independently by the Institute of Psychiatry (IoP) clinical trials unit. Blind assessments of outcome will be conducted at:

- 1. At the time of randomisation
- 2. At the end of treatment
- 3. After three months

Structure and contents of the workshops have been developed as a collaborative care intervention. This includes a carer manual with modules on: coping, medical risk, understanding change, communication, emotion processing, problem solving, interpersonal relationships, managing eating and other difficult behaviours, supplemented with skills-based workshops. The workshops teach practical skills such as key elements of motivational interviewing (MI) and cognitive behaviour therapy (CBT).

Procedure: potential participants from Eating Disorder Association (EDA) and South London and

Maudsley NHS Trust (SLAM). Carers will be divided into 8 groups of 15 carers. There will be six fortnightly sessions spread over a period of three months. Each session will last for two hours.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Carers:

- 1. General Health Questionnaire (GHQ-12; Goldberg et al, 1988)
- 2. Experience of Caregiving Inventory Eating Disorder Version (ECI-EDV)

Patients:

- 1. Short Evaluation of Eating Disorder (SEED; Bauer et al., 2005)
- 2. Global Assessment Scale (adapted from Spitzer et al. 1986)

Key secondary outcome(s))

Process measures:

Carers: expressed emotion, 5-minute speech sample (Mangana et al, 1986) Acceptability measures: the attendance at workshops will be monitored. Family satisfaction questionnaire will be used.

Completion date

31/12/2006

Eligibility

Key inclusion criteria

The participant must currently be caring for a relative with an eating disorder

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Kev exclusion criteria

- 1. People who are not caring for a relative with an eating disorder
- 2. Non-English speakers

Date of first enrolment

22/10/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Department Academic Psychiatry
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

King's College London (UK)

ROR

https://ror.org/0220mzb33

Funder(s)

Funder type

University/education

Funder Name

Institute of Psychiatry

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults28/02/2015YesNo