

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

Submission date 04/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/06/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/10/2016	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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)

Secondary outcome measures

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.

Overall study start date

22/10/2004

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

Age group

Adult

Sex

Both

Target number of participants

A total of 120 carers divided into 8 groups of 15 carers

Key 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**

England

United Kingdom

Study participating centre

Department Academic Psychiatry

London

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Sponsor information**Organisation**

King's College London (UK)

Sponsor details

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Sponsor type
University/education

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Funder(s)

Funder type
University/education

Funder Name
Institute of Psychiatry

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?
Results article	results	28/02/2015		Yes	No