

A pilot randomised controlled trial of the CD-ROM based intervention for carers of people with anorexia nervosa (AN)

Submission date 13/05/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 30/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/04/2013	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

Contact name

Dr Ulrike Schmidt

Contact details

Section of Eating Disorders
Box 059
Division of Psychological Medicine
Institute of Psychiatry
De Crespigny Park
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0160
U.Schmidt@iop.kcl.ac.uk

Additional identifiers

Protocol serial number

03/0332

Study information

Scientific Title

Study objectives

Carers randomised to receive the computerised intervention will show greater improvements on primary and secondary outcomes compared to the group receiving EDA support.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Pilot randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anorexia nervosa (AN)

Interventions

CD ROM group: The computerised intervention for carers of people with anorexia nervosa has been developed in the SLAM Eating Disorders Unit. This CD-ROM contains 9 interactive modules, which teach carers disease- and self-management skills. It includes information on how to communicate with the young person about their AN, how to support them at meal times to facilitate weight gain and re-establish healthy eating, how to manage crises and conflict, how to assess and manage risk, information on the use of the mental health act, how to address the carers' own needs, how to work with NHS and voluntary services and the role of different practitioners in the Eating Disorders team.

EDA support group: Informal support will be accessed from the EDA (EDA-support) via their helplines and carer support groups where available.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Carer-related measures: Hospital Anxiety and Depression scale (Zigmond & Snaith, 1983)

Key secondary outcome(s)

Standard Family Interview for Expressed Emotion (Hodes et al., 1991); Carer Coping (Pearlin et al., 1991), Experience of Care Giving (Szmukler et al., 1996); MEPS-ED (Platt et al., 1975), uptake

of CD-ROM; attitudes to self-help (Williams et al., unpublished). These measures will be given prior to the carer intervention and 3 months later.

Completion date

30/06/2006

Eligibility

Key inclusion criteria

Carers of patients with AN and eating disorder not otherwise specified (EDNOS) AN recruited via the Eating Disorders Association (EDA)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Carers of people with other eating disorders

Date of first enrolment

30/06/2005

Date of final enrolment

30/06/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Section of Eating Disorders

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Government

Funder Name

Health Services Research Committee South London and Maudsley NHS Trust (UK)

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	01/12/2011		Yes	No