

A preliminary randomised controlled trial of the efficacy of a CD-ROM based cognitive-behavioural self-help intervention for bulimia nervosa

Submission date 15/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 15/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/12/2008	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

LREC 217/00

Study information

Scientific Title

Study objectives

Hypothesis 1:

Patients receiving the CD-ROM treatment as the first step in treatment will show greater symptomatic improvement compared to patients on the waiting list at 3 months, and at 7 months patients in both groups will have similar outcomes.

Hypothesis 2:

Patients in the CD-ROM group will need fewer therapist sessions than those who do not have the CD-ROM as the first step of treatment.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the Institute of Psychiatry Research Ethics Committtee on the 17th October 2003 (ref: 217/00).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Bulimia nervosa

Interventions

ARM A:

CD-ROM self-care treatment: This treatment consists of eight modules, combining cognitive-

behavioural, motivational and educational strategies which the patients work through in order. Each module requires about 45 minutes at the computer. Patient workbooks and homework accompany each session. Self-assessment tools in the programme provide patients with printed feedback on their progress, detailing levels of bulimic symptoms, depression and anxiety.

Patients in this group will access the treatment programme in the eating disorder unit. They will be introduced to the programme and booked in for further computer appointments by a non-clinical administrator.

Patients will be encouraged to complete the programme over eight to 12 weeks. Thereafter, the need for further treatment will be determined using operational criteria adapted from a recent study on manual-based self-help.

Those who have shown more than 50% improvement on both objective bingeing and vomiting/laxative abuse (whichever is the more important compensatory behaviour in their case) on the EDE (Eating Disorders Examination) will be offered up to five sessions with a therapist over the next three to four months. Those with less than 50% improvement on both objective bingeing and vomiting/laxative abuse (whichever is the more important compensatory behaviour in their case) on the EDE will be offered up to 15 sessions with a therapist over the next three to four months.

ARM B:

Waiting list followed by therapist-aided CBT (Cognitive-Behavioural Therapy):

Patients allocated to this group will have a three months wait before they start a full course of standard CBT (16 sessions). Patients in this group will not have access to the computer-based intervention at any stage.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Eating Disorders Examination Global Score
2. Frequencies of binges and vomiting over the previous 28 days

Secondary outcome measures

1. Eating Disorders Examination Subscale scores
2. Proportion of patients in remission from bingeing, vomiting and laxative abuse
3. Treatment adherence

Overall study start date

01/01/2004

Completion date

01/04/2006

Eligibility

Key inclusion criteria

Referrals to the Maudsley Eating Disorders Unit will be eligible for inclusion in the study if they fulfil DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, IVth Edition) criteria for BN (Bulimia Nervosa), or partial BN (eating disorder not otherwise specified).

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

Actual number recruited = 97; power calculation suggests 94 needed.

Key exclusion criteria

1. Insufficient knowledge of English or literacy levels insufficient to allow understanding of the CD-ROM programme
2. Anorexia nervosa or psychosis
3. Active suicidality
4. Severe substance dependence or diabetes
5. Pregnancy

Date of first enrolment

01/01/2004

Date of final enrolment

01/04/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre**Section of Eating Disorders**

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.iop.kcl.ac.uk/>

ROR

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

Funder(s)**Funder type**

Research organisation

Funder Name

Psychiatry Research Trust (UK)

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	01/12/2008		Yes	No

