ISRCTN51564819 https://doi.org/10.1186/ISRCTN51564819

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

Registration date
15/01/2004

Overall study status
Completed

Last Edited
10/12/2008

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 0181
U.Schmidt@iop.kcl.ac.uk

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 binging 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 binging 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
Institute of Psychiatry
De Crespigny Park
London
England
United Kingdom
SE5 8AF
G.Dale@iop.kcl.ac.uk

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