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Internet-based CBT self-help treatment for students with bulimia nervosa

Submission date
29/09/2006

Recruitment status
No longer recruiting

Registration date
29/09/2006

Overall study status
Completed

Last Edited
18/12/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Bulimia nervosa (BN) is an eating disorder that causes significant impairment and distress among sufferers. Cognitive-behavioural therapy (CBT) is the treatment of choice and early access to therapy seems to improve outcomes. However, most young people with eating disorders do not access effective treatment and in many areas, the availability of CBT is limited. The main aim of this study was to evaluate how well internet-based cognitive-behavioural therapy (iCBT), supplemented with e-mail support, works among students with BN or similar disorders. The secondary aim of the study was to evaluate how immediate delivery of iCBT compares to delaying this. This was done to introduce similar conditions to those that patients in the National Health Service (NHS) experience.

Who can participate?
For this study we recruited students of any age and gender that were studying at five London-based universities that were invited to take part in the study.

What does the study involve?
Participants were assessed and then allocated at random to two groups. One group received immediate iCBT and the other group was put on a waiting list to receive the same treatment. We compared the outcomes of people in the groups at two points. The first comparison was made after the first group received treatment and the second group had been on the waiting list for the same time (three months). The second comparison was done after the second group (the waiting list group) had completed the treatment; this time we compared the outcomes of the two groups once both had completed the treatment. All participants received the same treatment except that some received it immediately and others waited for three months to receive this.

What are the possible benefits and risks of participating?
Participants who enrolled in the study received access to an innovative form of treatment (iCBT). Many participants had not received any form of treatment previous to their involvement in the study. There were no side effects expected from this treatment. However, it was expected that people in the waiting list were not going to experience a rapid improvement because they were not receiving treatment.

Where is the study run from?
We recruited students from five universities based in London: Kings College London, The University of the Arts, Goldsmiths University, St Georges University and Laban.

When is the study starting and how long is it expected to run for?
The study lasted for three years and it was run between September 2005 and September 2008.

Who is funding the study?
South London and Maudsley NHS Foundation Trust, CONACyT (Consejo Nacional de Ciencia y Tecnología) and the National Institute for Health Research Biomedical Research Centre.

Who is the main contact?
Professor Ulrike Schmidt
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0042166634

Study information

Scientific Title

Study objectives
Current hypothesis as of 18/12/2013:
The main hypothesis was that people who received internet Cognitive Behavioural Therapy (iCBT) would have better outcomes than those on the waiting list. The secondary hypothesis was that people who received delayed iCBT would have poorer uptake of treatment and poorer outcomes compared to those who received immediate access to the treatment.

Previous hypothesis:
Does internet-based Cognitive Behavioural Therapy improve symptoms for students with Bulimia Nervosa more than a self-help manual?

Updated 18/12/2013: the anticipated start date was changed from 01/08/2005 to 01/09/2005 and the anticipated end date was changed from 31/07/2007 to 01/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Mental and Behavioural Disorders: Bulimia nervosa

Interventions
This is a preliminary RCT.
The intervention group will receive a package of CBT by the internet over 8-12 weeks, with the support of an internet bulletin board and weekly e-mail exchange with a clinician.
The control group will receive a self-help manual for BN without any additional support.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Eating Disorders Examination (EDE)
2. WHO Quality of Life measure - brief version (WHOQOL-bref)
3. Qualitative questionnaire along with semi-structured qualitative interviews

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2005

Completion date
01/09/2008

Eligibility

Key inclusion criteria
The sample will be recruited by e-mails to the entire student population of King's College London and consist of students with a diagnosis of BN or EDNOS, who fulfill our inclusion criteria:
1. DSM IV criteria for bulimia or eating disorders not otherwise specified (EDNOS) with bingeing
2. Student (any age or sex)
3. Body Mass Index of 18.5 or greater anorexia

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
100

Key exclusion criteria
1. Insufficient knowledge of English to follow computerised programme
2. Anorexia nervosa, psychotic symptoms, servere depression, suicidal thinking or major self harm risk
3. Substance dependency
4. Pregnancy
5. Serious physical illness
6. Regular vomiting greater than 4 times in 24 hourse on a regular basis if a subsequent blood

test reveals hypokalaemia
7. Current or recent CBT
8. Plans to change medication in the coming 3 months

Date of first enrolment
01/09/2005

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Eating Disorders Unit
London
United Kingdom
SE5 8AZ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
South London and Maudsley NHS Trust (UK), NHS R&D Support Funding

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	01/02/2011		Yes	No