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Evaluation of internet-based, guided, self-help, cognitive behavioural therapy for bulimia nervosa and similar eating disorders in a specialist outpatient setting

Submission date
20/06/2013

Recruitment status
No longer recruiting

Registration date
17/07/2013

Overall study status
Completed

Last Edited
03/01/2023

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
About 10% of women and 1% of men are affected by eating disorders (EDs). Bulimia nervosa (BN) is a common ED that involves repeated episodes of uncontrolled eating and compensatory behaviors such as avoiding eating, over a period of at least three months. Cognitive behavioral therapy (CBT), which helps in managing behavioral problems, works well and is the treatment of choice for BN and similar EDs, but it is rarely offered to people coming to specialist outpatient facilities due to a relative lack of CBT therapists. In internet-based CBT guided self-help (CBT-GSH), each therapist can treat about four times as many patients as compared to standard therapy. This may lead to shorter waiting lists and that means more patients can be offered CBT. Previous university studies have shown positive results from CBT-GSH. However, in the clinic the impacts are still largely unknown and have rarely been tested. The aim of this study is to find out whether CBT-GSH is good enough to put into practice as a complement to the usual treatment.

Who can participate?
Participants should at least be 18 years of age, and have BN or a similar ED.

What does the study involve?
Participants are randomly allocated to one of two groups: internet-based CBT-GSH or to an intensive day patient program (DPP). The CBT-GSH group have weekly contact over the internet with a therapist and work with CBT-based exercises for a maximum of 24 weeks. The main differences between the two types of CBT-GSH are that one is purely interactive and associated with license costs for the clinic whereas the other comes with a paperback manual and is essentially free of charge. The DPP group participate three hours daily for 16 weeks in a treatment that provides group and individual therapy, meals, body knowledge and art therapy. DPP is not experimentally validated, but is one of the standard treatments at the clinic.

What are the possible benefits and risks of participating?
The possible benefit of participating is a chance to quickly get access to a form of CBT or to a

well-tried intensive group treatment. There are no known risks of participating. Participants are informed that they can withdraw from the study at any time, without any negative consequences. Participants who do not wish to participate receive standard treatment at the clinic.

Where is the study run from?
Stockholm Center for Eating Disorders, the Stockholm county council, Sweden.

When is the study starting and how long is it expected to run for?
The study started in 2009 and it is expected to run until 2016. The recruitment was carried out from October 2009 through February 2013.

Who is funding the study?
Financial support was provided for clinical research by Stockholm County Council (Sweden) and partly from a government grant via Stockholm County Council board administration.

Who is the main contact?
Ms Louise Högdahl
louise.hogdahl@ki.se

Contact information

Type(s)
Scientific

Contact name
Ms Louise Högdahl

Contact details
Center for Psychiatric Research Stockholm
Resource Center for Eating Disorders
Norra Stationsgatan 69, plan 7
Stockholm
Sweden
11364
+46704842763
louise.hogdahl@ki.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of internet-based, guided, self-help, cognitive behavioural therapy for bulimia nervosa and similar eating disorders in a specialist outpatient setting: a randomized controlled trial

Study objectives
Internet-based, guided, self-help, cognitive behavioural therapy is a cost-effective treatment for bulimia nervosa and similar eating disorders in clinical settings. It may be a sufficient treatment for some patients, the first step in a stepped care treatment for others, and it represents a new way of providing evidence based treatment for more patients than what is currently doable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Stockholm Ethical Review Board, ref: 2008/669-31/4

Study design
Randomized controlled single-center trial with a three-year follow-up

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Bulimia nervosa and similar eating disorders not otherwise specified

Interventions
The current project has three treatment arms.
1. One is a bibliotherapy-based guided self-help (GSH) cognitive behavioral therapy (CBT) with Internet support. The CBT-based self-help manual 'Overcoming Binge Eating', Swedish translation is used. It contains facts about eating disorders (EDs), and a six-step self-help program with detailed instructions, assignments and checklists.
2. Salut BN is a purely interactive CBT-GSH in seven-steps with assignments, diagrams and checklists.
In both treatments, the patients have weekly contact with their therapist for feedback, guidance and support. The maximum length of treatment is 24 weeks. Therapists are three psychologists who were trained in CBT prior to the study. Approximately 11 therapist hours are required per

patient in these two treatments.
3. The day patient program (DPP) is a psychodynamic intensive group treatment with group- and individual therapy, meals, body knowledge, and art therapy. Eight patients participate in each group, 3.5 hours daily. The staff at DPP is a medical doctor, an art therapist, psychologists, psychotherapists, physiotherapists, dieticians, psychiatric nurses and social workers. Length of treatment is 16 weeks. Approximately 200 therapist hours are required per patient in this treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pre- and post-treatment symptoms of eating disorder
2. Comorbidity, self-image
3. Clinical impairment
4. Motivation
They are assessed with the computerized 'Stepwise' system which contains several clinical- and self -assessments:
1. Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I), a clinical interview for assessment of comorbid psychiatric disorders
2. Structured Eating Disorder Interview (SEDI), a clinical interview for assessment of DSM-IV eating disorder diagnosis
3. The Eating Disorder Examination Questionnaire (EDE-Q), a 36-item self-assessment of dietary restraint, eating concern, shape concern, weight concern, and frequency of episodes of disturbed eating- and compensatory behaviours during the past 28 days
4. The Structural Analysis of Social Behaviour (SASB) Intrex introject, a self-assessment of self-image in 36 statements describing self-directed behaviours
5. The Comprehensive Psychopathology Rating Scale self-assessment for Affective syndromes (CPRS-S-A), a self-assessment that measures depression, anxiety, and obsession-compulsion during the past three days on a 7-step scale
6. The Clinical Impairment Assessment (CIA), a 16-item self-report that measure impairment due to eating disorder
7. The Bulimia Nervosa Stages of Change Questionnaire (BNSOCQ), a 20-item self-report that assess motivation to recover from bulimia nervosa.

Secondary outcome measures
1. Predictors of treatment outcome (one year post-treatment)
2. Long-term follow-up (three years post-treatment)
Methods used for measuring the secondary outcome measures are the same as mentioned above.

Overall study start date
14/10/2009

Completion date
25/11/2016

Eligibility

Key inclusion criteria
1. Diagnosed with bulimia nervosa, sub-threshold bulimia, or binge eating disorder if there has been a history of recurrent compensatory behaviour within the past year.
2. Body mass index (BMI) 17.5-34
3. Minimum 18 years of age
4. Fluent in Swedish
5. Continuous access to the Internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 (149 females and 1 male)

Total final enrolment
150

Key exclusion criteria
1. Severe symptoms of depression, anxiety and/or obsession-compulsion
2. Alcohol- or drug dependency
3. Psychosis
4. Suicidal thoughts, suicide attempt within the past year
5. Previous participation in any of the current treatment interventions, or other ongoing treatment for eating disorder

Date of first enrolment
14/10/2009

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
Sweden

Study participating centre
Center for Psychiatric Research Stockholm
Stockholm

Sweden
11364

Sponsor information

Organisation
Stockholm County Council (Sweden)

Sponsor details
Hantverkargatan 45
Box 22550
Stockholm
Sweden
10422
-
landstinget@sll.se

Sponsor type
Government

ROR
https://ror.org/02zrae794

Funder(s)

Funder type
Government

Funder Name
Financial support was provided for clinical research by Stockholm County Council (Sweden) and partly from a government grant via Stockholm County Council board administration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	1-year follow-up	21/12/2022	03/01/2023	Yes	No