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Bridging waiting time with internet-based self-help for bulimia nervosa, binge eating disorders and other specified feeding and eating disorders

Submission date
25/02/2016

Recruitment status
No longer recruiting

Registration date
26/02/2016

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Eating disorders are a group of common conditions which are defined by an abnormal attitude towards food. Anyone can develop and eating disorder although they are far more common in women, particularly those who are in early adulthood. Bulimia nervosa is a serious mental health condition in which a person excessively overeats (binging) and then takes action to remove the food from the body quickly, such as by vomiting or using laxatives (purging). Binge eating disorder also involves binging but lacks the purging element, making it a very different disorder. It can take time for patients affected by these disorders to receive therapy, and so self-help programs could help to bridge this time gap. Self-help programs might be used as first step of treatment or to bridge waiting time for face-to-face outpatient treatment. It is unclear however, how this type of treatment could affect later outpatient therapy and whether it leads to a faster reduction of bulimic symptoms. The everyBody-Plus program is a treatment based on cognitive behavioural therapy (a type of therapy that aims to change the way people think and behave). It involves education about different aspects of eating disorders as well as self-monitoring, a personal journal and behavioural exercises. The aim of this study is to find out whether the everyBody-Plus program can help to reduce eating disorder symptoms and stop sufferers from binging and purging while they await outpatient therapy.

Who can participate?
Women who are seeking treatment for bulimia, binge eating disorder or other specified feeding or eating disorder (OSFED).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the everyBody-Plus program. This consists of eight weekly sessions that cover topics relating to eating and exercise patterns, coping with stress, improving body image and binge eating /purging. The participants are also asked to keep a journal and monitor their eating disorder symptoms, which they will receive weekly, personal feedback on. Those in the second group do not take part in any additional treatment during the wait for outpatient therapy, however they are also asked to monitor their eating disorder symptoms and keep a journal. At the start of the

study, after the program ends and then six and 12 months later, participants in both groups complete a number of questionnaires in order to assess their eating disorder symptoms. The amount of time from the start of the study until patients show a clinical improvement (i.e. not binging/purging for at least four weeks and having a healthy weight) is also recorded for all participants.

What are the possible benefits and risks of participating?
Participants will benefit from being awarded points for each completed assessment which they are able to redeem for rewards. There are no direct risks to participants taking part in this study.

Where is the study run from?
1. Technical University Dresden (Germany)
2. King's College London (UK)

When is the study starting and how long is it expected to run for?
September 2015 to June 2020

Who is funding the study?
European Union's Horizon 2020 Framework Programme for Research and Innovation (Belgium)

Who is the main contact?
Prof. Corinna Jacobi (scientific), corinna.jacobi@tu-dresden.de
(no longer a contact as of 06/08/2021:
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Using Internet-based self-help to bridge waiting time for face-to-face outpatient treatment for Bulimia Nervosa, Binge Eating Disorder and Other Specified Feeding and Eating Disorders (OSFED)

Study objectives
everyBody-Plus will be associated with both a more rapid reduction of core eating disorder symptoms and higher abstinence rates compared with the waiting list group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at Technische Universität Dresden, 25/02/2016, ref: EK84032016

Study design
Pragmatic multi-country multi-centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bulimia nervosa, binge eating disorder or other specified feeding or eating disorder (OSFED)

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants will receive everyBody Plus, based on eating disorder-specific cognitive-behavioural therapy. It consists of 8 weekly sessions and includes reading assignments, self-monitoring, a personal journal and behavioural exercises. Topics covered are healthy eating and exercise patterns, dealing with “forbidden foods” and binge eating/purging, improving body image, coping with stress and negative emotions, and self-esteem. Patients will receive weekly personal feedback based on their self-monitoring and journal entries. The program is supplemented by a moderated asynchronous discussion board to exchange experiences and thoughts with other patients. Trained clinical psychologists supervised by the study PIs will provide personal feedback and moderate the online discussion board. Further assessments will take place at post-intervention, 6- and 12-month follow-up. The Internet-based and therefore site-independent intervention will be guided by staff at TU Dresden (German version) and King’s College London (English version).

Control group: Participants will only be prompted to complete the weekly self-monitoring of core ED symptoms as well as the post- and follow-up assessments.

Intervention Type
Behavioural

Primary outcome(s)

Number of weeks after randomisation until a patient achieves a clinical relevant improvement* in core symptoms for the first time will be measured using a weekly symptom monitoring that includes questions about the number of binge eating and compensatory behaviours (vomiting, fasting, excessive exercise, use of laxatives, diuretics or appetite suppressants) and the current body weight of the participant.

*Clinically relevant improvement is defined as abstinence from binge eating and compensatory behaviours (vomiting, fasting, excessive exercise, use of laxatives, diuretics or appetite suppressants) and a BMI of over 18.5, over a period of at least four weeks. Weekly symptom monitoring continues until 12 months post randomisation.

Key secondary outcome(s))

1. Number of therapy sessions after randomisation until a participant achieves a clinical relevant improvement for the first time. To obtain this information, cooperating therapists will be asked to provide information about the number of therapy session utilized by the participant once per quarter.
2. Frequencies of core eating disorder symptoms (i.e., binge eating, compensatory behaviours) in the previous month will be measured by self-report at baseline, post-intervention, 6 and 12 months follow up
3. Eating disorder psychopathology will be measured using the Eating Disorder Examination Questionnaire (EDE-Q) at baseline, post intervention, 6 and 12 months follow up
4. Body image concerns will be measured using the Weight Concerns Scale (WCS) at baseline, post intervention, 6 and 12 months follow up
5. Intuitive Eating will be measured using the Intuitive Eating Scale (IES) at baseline, post intervention, 6 and 12 months follow up
6. Fruit- and vegetable consumption will be measures by self-report at baseline, post-intervention, 6 and 12 months follow up
7. Depression will be measured using the PHQ-9 at baseline, post intervention, 6 and 12 months follow up
8. Anxiety will be measured using the GAD-7 at baseline, post intervention, 6 and 12 months follow up
9. Alcohol consumption will be measures using the The Alcohol Use Disorders Identification Test (AUDIT-C) at baseline, post intervention, 6 and 12 months follow up
10. Quality of life will be measured by the Assessment of Quality of Life-8D (AQoL-8D) questionnaire at baseline, post intervention, 6 and 12 months follow up
11. Self-Esteem will be measured using the Rosenberg Self-Esteem Scale (RSE) at baseline, post intervention, 6 and 12 months follow up
12. Self-regulation skills will be measures using the Short Self-Regulation Questionnaire (SSRQ) at baseline, post intervention, 6 and 12 months follow up

The following additional outcomes will be measured at start of trial, half-way through and at end of the trial:
1. Participating therapists' confidence in treating eating disorders (self-report on relevant therapeutic skills and emotions while treating patients with Eating Disorders)
2. Therapists' perceived benefits of everyBody Plus for patients (STEP, modified for online interventions)

For health-economic analyses, the Client Service Receipt Inventory (CSRI) will be administered at baseline, post intervention and at the 6 and 12 month follow ups.

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Women aged 18 or older
2. Seeking treatment from cooperating psychotherapists for Bulimia nervosa, Binge Eating Disorder or OSFED
3. Access to the Internet
4. Informed consent (online)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
114

Key exclusion criteria
1. Women not eligible for treatment due to low symptom severity, according to judgement of cooperating therapist
2. Women with a BMI under 18.5
3. Women with an indication for inpatient eating disorder treatment according to judgement of cooperating therapist
4. Women with significant psychiatric comorbidity needing treatment in its own right (e.g., substance dependence), major psychiatric disorders (e.g., psychosis) or are acutely suicidal women
5. Women receiving antidepressant medication who have not been on a stable dose for at least four weeks

Date of first enrolment
16/11/2016

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
United Kingdom

England

Germany

Study participating centre
Technical University Dresden (Technische Universität Dresden)
Chemnitzer Straße 46a
Dresden
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Study participating centre
King's College London
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Sponsor information

Organisation
Technical University Dresden (Technische Universität Dresden)

ROR
https://ror.org/042aqky30

Funder(s)

Funder type
Government

Funder Name
European Union's Horizon 2020 Framework Programme for Research and Innovation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Corinna Jacobi (corinna.jacobi@tu-dresden.de).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		26/02/2024	06/03/2024	Yes	No
Protocol article	protocol	26/02/2018	18/06/2019	Yes	No