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Internet-based aftercare for eating disorders following inpatient treatment: randomized controlled trial for bulimia nervosa

Submission date
05/02/2007

Recruitment status
No longer recruiting

Registration date
02/04/2007

Overall study status
Completed

Last Edited
25/09/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
While most women with bulimia nervosa experience short-term benefits from treatment, relapse rates are high and especially the first months after achieving abstinence from binge eating and purging are critical. The aim of our study is to examine whether an internet-based aftercare program for women who have successfully completed specialized inpatient treatment can help reduce relapse risk. The program runs over 9 months and is guided by clinical psychologists specialized in eating disorder treatment.

Who can participate?
Women aged 18 and over who received inpatient treatment for bulimia nervosa in 13 cooperating psychosomatic hospitals in Germany

What does the study involve?
Participants are randomly allocated to one of two groups. The women in the intervention group receive the internet-based aftercare program for 9 months after hospital discharge in addition to their usual treatment. The women in the control group only receive their usual treatment. Both groups are interviewed about their eating disorder symptoms via telephone 9 and 18 months after hospital discharge and we will then compare the two groups.

What are the possible benefits and risks of participating?
It is hoped that women who participate in the program will decrease their relapse risk. The women in the control group have an opportunity to receive the treatment after the study is completed. During the study period, participants are asked to monitor eating disorder symptoms. This may cause temporary discomfort in some individuals.

Where is the study run from?
The study is run by the Institute of Clinical Psychology and Psychotherapy at Technische Universität Dresden (Germany).

When is the study starting and how long is it expected to run for?
April 2007 to December 2013

Who is funding the study?
Federal Ministry of Education and Research (Germany)

Who is the main contact?
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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
011GV0603

Study information

Scientific Title
Internet-based aftercare for eating disorders following inpatient treatment: randomized controlled trial for bulimia nervosa

Acronym
IN@

Study objectives

Current hypothesis as of 17/04/2014, according to the study protocol approved in July 2007:
Bulimic patients participating in an Internet-based aftercare program after inpatient treatment will have a significantly higher abstinence rate in comparison to a treatment-as-usual control group at post-treatment (after 9 months) and at 18-month follow-up.

Previous hypothesis:
Bulimic patients participating in an Internet-based relapse prevention program after inpatient treatment will have a significantly lower rate of of binges and purges in comparison to a treatment-as-usual control group at post-treatment (after 9 months) and at one-year follow-up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethikkommission, Technische Universität Dresden, ref: EK247112006

Study design
Prospective randomised superiority trial with two parallel arms

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Bulimia nervosa (eating disorders)

Interventions
Current interventions as of 17/04/2014, according to the study protocol approved in July 2007:
1. Nine-month Internet-based aftercare program in addition to Treatment As Usual (TAU)
2. Treatment As Usual (TAU)

Previous interventions:
1. Nine-month Internet-based relapse prevention program
2. Treatment As Usual (TAU)

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Current primary outcome measures as of 17/04/2014, according to the study protocol approved in July 2007:
The primary efficacy endpoint will be the percentage of patients abstinent from core bulimia nervosa behaviors at the end of the treatment (9 months). Abstinence is defined as the absence of binge eating and inappropriate compensatory behaviour (e.g., vomiting) for at least two months at post-intervention.

Previous primary outcome measures:
The primary efficacy endpoint will be the frequency of relapses at the end of the treatment (12 month). Relapses are defined as the presence of binging and/or inappropriate compensatory behaviour (i.e. including vomiting) at least twice per week for three months during the 12 month follow-up.

Secondary outcome measures
Current secondary outcome measures as of 17/04/2014, according to the study protocol approved in July 2007:
1. Abstinence from core bulimia nervosa behaviours at follow-up (18 months after randomization)
2. Eating disorder diagnoses (as measured by Structured Inventory for Anorexic and Bulimic Syndromes) at the end of treatment and follow-up
3. Changes in eating disorder related behaviours and attitudes (as measured by Eating Disorder Inventory and Eating Disorder Examination Questionnaire) between baseline and end-of-treatment/follow-up
4. Changes in general psychopathology (as measured by global severity index of the BSI) between baseline and end-of-treatment/follow-up
5. Changes in depressive symptoms (as measured by BDI) between baseline and end-of-treatment/follow-up
6. Changes in impulsiveness (as measured by Barrat Impulsiveness Scale) between baseline and end-of-treatment/follow-up
7. Changes in self-esteem (as measured by Rosenberg Self Esteem Scale) between baseline and end-of-treatment/follow-up

Previous secondary outcome measures:
1. Expert interviews for the assessment of primary and secondary outcomes (T0, T1, T3):
1.1. Structured Inventory for Anorexic and Bulimic Syndromes (SIAB-EX)
1.2. Psychiatric Status Rating (PSR)
1.3. Structured Clinical Interview for DSM-IV (SCID-I)
2. Self-rating instruments (T0, T1, T2a-e, T3):
2.1. Eating Disorder Inventory (EDI-2)
2.2. SIAB-S self-rating
2.3. Symptom-Checklist (SCL-56)
2.4. Barrett Impulsiveness Scale (BIS-11)

Overall study start date
01/04/2007

Completion date
31/12/2013

Eligibility

Key inclusion criteria
1. Age at least 16 years
2. Informed consent by patient and - if necessary - by her legal guardian
3. Female
4. Diagnosis of bulimia nervosa (BN) according to DSM-IV-TR at the time of admission to inpatient treatment
5. Successful completion of inpatient treatment as defined by at least 50% reduction in binge eating and purging during the last two weeks prior to discharge from inpatient treatment

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
To be allocated to intervention and control conditions: 258

Key exclusion criteria
1. Mental or physical condition that does not allow the patient's participation in the trial
2. Acute psychosis, chronic organic or schizophrenic psychosis
3. Severe suicidal ideation or behaviour
4. Premature discharge from inpatient treatment

Date of first enrolment
01/08/2007

Date of final enrolment
01/01/2012

Locations

Countries of recruitment
Germany

Study participating centre
Technische Universität Dresden
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Sponsor information

Organisation
Federal Ministry of Education and Research (Germany)

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Sponsor type
Government

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Federal Ministry of Education and Research (Germany)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

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	22/09/2017		Yes	No