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Targeted prevention for women with subclinical anorexia nervosa - Student Bodies-AN (SB-AN)

Submission date
03/04/2014

Recruitment status
No longer recruiting

Registration date
22/04/2014

Overall study status
Completed

Last Edited
08/06/2022

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
Anorexia nervosa (AN) is a condition with serious medical and psychological complications, high mortality and rather poor long-term outcome. Despite the seriousness of the disorder, there have not been a lot of studies. Early treatments before the onset of the full disorder are therefore urgently needed. Existing treatments do not specifically target women most at risk of AN (who have lower body weight and/or high restrained eating in addition to high weight and shape concerns). An initial study showed that recruitment of women at risk of AN is feasible, and that compliance with the treatment was good. The aim of this study is to assess how well a new approach, called Student Bodies AN (SB-AN), works.

Who can participate?
Women aged 18 and diagnosed with AN.

What does the study involve?
Participants will be randomly allocated to one of two groups: Student Bodies AN (SB-AN) group or waiting-list group. SB-AN is an internet-based cognitive-behavioural prevention program which consists of 10 weekly sessions and a booster session and which includes interactive components moderated by trained clinical psychologists. Further assessments will take place at the end of the study , then 6 and 12 months later. Participants in the waiting list group will be offered SB-AN after 12 months.

What are the possible benefits and risks of participating?
There are no risks for the participants. Participants whose eating disorder gets worse during the treatment will be referred to outpatient treatment clinics or will be helped to find a therapist. Future women at risk of AN may benefit from the development and evaluation of a treatment that works at low cost.

Where is the study run from?
Participants will be recruited through German universities (planned cities: Dresden, Halle, Leipzig, Berlin, Hamburg) and two higher-risk environments (eg advisory center for eating disorders ANAD e. V., Munich) via local media.

When is the study starting and how long is it expected to run for?
November 2012 to November 2015.

Who is funding the study?
Else Kröner-Fresenius-Stiftung (Germany)

Who is the main contact?
Prof. Dr. Corinna Jacobi
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2012_A01

Study information

Scientific Title
Targeted prevention for women with subclinical anorexia nervosa - Student Bodies-AN (SB-AN): a randomized controlled trial

Acronym
SB-AN

Study objectives
Women with subclinical anorexia nervosa participating in an indicated, internet-based prevention program (SB-AN) will show significantly fewer eating disorder symptoms compared to a wait-list control group at 12-month follow-up.

At 12-month follow-up, initially underweight women (17.5 ≤ BMI ≤ 19) of the SB-AN intervention group will show a significantly higher BMI in comparison to a wait-list control group.

On 23/06/2015 the target number of participants was changed from 143 to 168.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dresden Technical University Ethics Committee, main approval: 26/09/2012, approvals for amendments: 25/04/2013, 10/09/2013, 21/02/2014, Ref: EK264082012

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Women with subclinical anorexia nervosa and/or at risk for the development of anorexia nervosa

Interventions
Eligible women (aged 18 and above) will be screened at universities in different cities in Germany (planned cities: Dresden, Halle, Leipzig, Berlin, Hamburg) and two higher-risk environments. Following informed consent, primary and secondary outcomes as well as inclusion and exclusion criteria will be assessed via interview and self-report questionnaires. Participants fulfilling the inclusion criteria will be randomized to one of the following two groups:

1. Student Bodies AN (SB-AN): the Internet-based cognitive-behavioral prevention programme (Student Bodies-AN) consists of 10 weekly sessions and a booster session and is moderated by trained clinical psychologists supervised by the study PI. Further assessments will take place at post-intervention, 6- and 12-month follow-up.
2. Waiting list condition: participants will be offered SB-AN after the 12-month follow-up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. The rates (%) of participants with a decrease in the Eating Disorder Examination (EDE) total score below a score of 1.87 between pre-intervention and 12-month follow-up
2. The rates (%) of underweight participants with a BMI increase of at least 0.8 kg/m² between pre-intervention and 12-month follow-up

Key secondary outcome(s)
The following outcomes will be measured at baseline, after the last session of SB-AN (10 weeks), six months after the program was finished and 12 months after the program was finished:
1. Eating Disorder Examination subscales (EDE-Weight Concern, EDE-Shape Concern, EDE-Eating Concern, EDE-Restraint)

2. Number of binges (for binge eating subgroup)
3. Frequency of participants fulfilling criteria for EDNOS

The following outcomes will be measured at baseline, after the fifth session of SB-AN, after the last session of SB-AN (10 weeks), six months after the program was finished, 12 months after the program was finished:
1. Weight Concern Scale (WCS)
2. Eating Disorder Inventory-2 (EDI-2), subscales: Drive for Thinness, Bulimia, Body Dissatisfaction
3. Beck Depression Inventory-II (BDI-II)
4. Brief Symptom Inventory (BSI)
5. Exercise Dependence Questionnaire (EDQ)
6. Frost Multidimensional Perfectionism Scale (FMPS)
7. Clinical Impairment Assessment (CIA)
8. Knowledge test

Completion date
15/11/2015

Eligibility

Key inclusion criteria
1. Age ≥ 18 years
2. Informed consent
3. Female gender
4. High weight and shape concerns (WCS > 42)
5. 17.5 ≤ BMI ≤ 21 OR 21 < BMI ≤ 25 AND restrictive eating (EDE-Q Restraint ≥ 2.6; = more than 1 SD above the mean of healthy controls)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
168

Key exclusion criteria
1. Current full-syndrome (DSM-IV) anorexia nervosa, bulimia nervosa or binge eating disorder
2. Serious medical or mental problems that would prohibit participation in the trial, i.e. current substance abuse, acute or chronic organic or schizophrenic psychosis

3. Severe suicidal ideation or behavior
4. No Internet access

Date of first enrolment
15/11/2012

Date of final enrolment
15/11/2015

Locations

Countries of recruitment
Germany

Study participating centre
Technische Universität Dresden
Dresden
Germany
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Sponsor information

Organisation
Else Kröner-Fresenius Foundation (Germany)

ROR
https://ror.org/03zcxha54

Funder(s)

Funder type
Charity

Funder Name
Else Kröner-Fresenius-Stiftung

Alternative Name(s)
Else Kroner-Fresenius Foundation, Else Kroener-Fresenius-Stiftung, Else Kröner Fresenius-Stiftung, EKFStiftung, StiftungEKFS, EKFS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Results and Publications

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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/06/2022	08/06/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes