

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

Submission date 03/04/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/04/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 08/06/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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
corinna.jacobi@tu-dresden.de

Study website
<http://www.studentbodies.tu-dresden.de>

Contact information

Type(s)
Scientific

Contact name
Prof Corinna Jacobi

Contact details
Technische Universität Dresden
Klinische Psychologie und Psychotherapie
Chemnitzer Straße 46
Dresden
Germany
01187
+49 (0) 351 463 38576
corinna.jacobi@tu-dresden.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 ($17.5 \leq \text{BMI} \leq 19$) 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

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

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

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 measure

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

Secondary outcome measures

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

Overall study start date

15/11/2012

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. $17.5 \leq \text{BMI} \leq 21$ OR $21 < \text{BMI} \leq 25$ AND restrictive eating (EDE-Q Restraint ≥ 2.6 ; = more than 1 SD above the mean of healthy controls)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

To be allocated to intervention and control conditions: N=168

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

01187

Sponsor information

Organisation

Else Kröner-Fresenius Foundation (Germany)

Sponsor details

Postfach 1852
61288 Bad Homburg v.d.H
Bad Homburg v.d.H.
Germany
61288
+49 (0)6172 8975 0
kontakt@ekfs.de

Sponsor type

Charity

Website

<http://www.ekfs.de/de/start.html>

ROR

<https://ror.org/03zcxha54>

Funder(s)**Funder type**

Charity

Funder Name

Else Kröner-Fresenius-Stiftung

Alternative Name(s)

Else Kroener-Fresenius-Stiftung, Else Kröner Fresenius-Stiftung, Else Kroner-Fresenius Foundation, EKFS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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

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		02/06/2022	08/06/2022	Yes	No