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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
03/04/2014		☐ Protocol		
Registration date 22/04/2014	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 08/06/2022	Condition category  Mental and Behavioural Disorders	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

# **Contact information**

# Type(s)

Scientific

#### Contact name

Prof Corinna Jacobi

#### Contact details

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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  $\leq$  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

# 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  $\leq$  BMI  $\leq$  21 OR 21 < BMI  $\leq$  25 AND restrictive eating (EDE-Q Restraint  $\geq$  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 01187

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes