

The "Healthcare Network Anorexia and Bulimia nervosa"-campaign - Focal-project 1: Prevention trial at 20 secondary schools in Hamburg

Submission date 04/10/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 12/01/2012	Overall study status Completed	
Last Edited 15/08/2017	Condition category Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims

Adolescents are especially vulnerable to develop eating disorders. School prevention programs have been found to be effective at reducing the occurrence of eating disorders. However, existing prevention programs were mainly focused on female participants. Their transference in the everyday life at school was therefore difficult. The aim of this study is to develop a time-effective eating disorder prevention program which addresses young females and males.

Who can participate?

School-attending adolescents in the 8th or 11th grade (age 14 and 17)

What does the study involve?

Students are randomly allocated to either a control group or an intervention group. The intervention comprises three 90-minute units which are delivered over a two-week period. The first unit occurs on its own while the second and third units occur straight after each other one week later. The prevention program comprises interactive and educational elements about eating disorders and their treatment. Participants pass through different exercises and reflect on the influences of the media, self-esteem, body perception and individual resources. Eating disorder risk, internalization of Western beauty ideals, body dissatisfaction, self-concept as well as anxiety and symptoms of depression are measured before and immediately after the intervention as well as at a six-month follow-up using self-report measures. Participants in the intervention group complete a questionnaire at baseline, at the end of the intervention and at six months after the intervention. Participants in the control group complete the questionnaire at equal intervals without receiving any intervention.

What are the possible benefits and risks of participating?

Participants might decrease their individual eating disorder risk after participation in the prevention program through improvements in coping with negative emotions and pressure from media, peers and family. They might also strengthen their individual resources like social support or the activation of existing functional coping strategies. All participants receive a flyer compromising information and treatment options for adolescents suffering from eating

disorders. If students themselves or a friend suffers from an eating disorder or teachers have an eating disorder suspicion in their classes the Principal Investigator is contactable to answer any questions. Such incidents are recorded and monitored throughout the study.

Where is the study run from?

University Medical Center Hamburg-Eppendorf, Department of Psychosomatic Medicine and Psychotherapy (Germany)

When is the study starting and how long is it expected to run for?

February 2012 to July 2014

Who is funding the study?

Federal Ministry of Education and Research (Germany)

Who is the main contact?

Prof. Bernd Löwe

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Contact information

Type(s)

Scientific

Contact name

Prof Bernd Löwe

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

The "Healthcare Network Anorexia and Bulimia Nervosa"-campaign - Focal-project 1: Prevention trail at 20 secondary schools in Hamburg: a cluster-randomized controlled trial

Study objectives

Primary hypothesis: The application of the school-based primary preventive campaign to a high risk student sample leads to a reduction of individual's risk factors for eating disorders in adolescence and gain of knowledge on the subject of eating disorders

Secondary hypothesis: The application of the school-based primary preventive campaign to a high risk student sample leads to an improvement of the body-related self-worth as well decrease in depressiveness and a reduction of the internalization of the ideal of slimness.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Psychotherapist Chamber of the Free and Hanseatic City of Hamburg, 26/07/2011

Study design

Cluster-randomized controlled trial with repeated measurements

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Anorexia nervosa, bulimia nervosa

Interventions

The prevention campaign which will be administered to the experimental group will consist of 3 teaching units of 90 minutes respectively. The first lesson unit will serve to assess the students current state of knowledge in the subject of eating and eating disorders. The preventive workshop will be given in the second teaching unit and consist of interactive exercises to attain knowledge about eating disorders, role plays, audiotexts focusing on certain aspects of the subject and an internet-self-test. The last lesson will conclude the module with an encounter with patients and a final debriefing.

The control group will be given the choice to participate in the workshop program after the trial will be concluded (in terms of a waiting list control condition) or to take part in a career exploration day offered by the research institute.

Intervention Type

Behavioural

Primary outcome measure

1. Risk status for the development of an eating disorder assessed by child version of the Eating Disorder Examination (ChEDE-Q)
2. Knowledge on the subject of eating disorders (Knowledge test)

Measured thrice for each participant in terms of a repeated measure design, 1 month before the intervention, immediately after the intervention and 6 months after the intervention.

Secondary outcome measures

1. Societal influences on body image and eating disturbances, measured using Sociocultural Attitudes Towards Appearance Questionnaire (SATAQ-G)
2. Self-worth, measured using MSWS
3. Depressiveness, measured using Patient Health Questionnaire (PHQ-9)
4. Anxiety, measured using Generalised Anxiety Disorder Assessment (GAD-7)
5. Health outcome, measured using EQ-5D

Measured thrice for each participant in terms of a repeated measure design, 1 month before the intervention, immediately after the intervention and 6 months after the intervention.

Overall study start date

01/04/2011

Completion date

31/12/2015

Eligibility**Key inclusion criteria**

1. Informed consent
2. Enrolment in grades 8 or 11

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

To be screened: 2340 , to be recruited: 2.240, to be evaluated: 1.792

Key exclusion criteria

Deficiencies in the command of the German language

Date of first enrolment

01/02/2012

Date of final enrolment

31/07/2014

Locations

Countries of recruitment

Germany

Study participating centre

University Medical Centre Hamburg-Eppendorf (Universitätsklinikum Hamburg-Eppendorf)

Department of Psychosomatic Medicine and Psychotherapy

Martinistrasse 52

Hamburg

Germany

20246

Sponsor information

Organisation

Federal Ministry of Education and Research (Germany)

Sponsor details

Bundesministerium für Bildung und Forschung - BMBF

Dienstsitz Berlin

Hannoversche Straße 28-30

Berlin

Germany

D-10115

Sponsor type

Government

ROR

<https://ror.org/04pz7b180>

Funder(s)

Funder type

Government

Funder Name

Bundesministerium für Bildung und Forschung

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

To be confirmed at a later date

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/02/2015		Yes	No
Results article	results	11/08/2017		Yes	No