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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

Registration date
12/01/2012

Overall study status
Completed

Last Edited
15/08/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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.

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Informed consent
2. Enrolment in grades 8 or 11

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

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
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Sponsor information

Organisation
Federal Ministry of Education and Research (Germany)

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Results and Publications

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?
Results article	results	11/08/2017		Yes	No
Protocol article	protocol	12/02/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes