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Early detection and intervention of anorexia nervosa

Submission date
06/01/2012

Recruitment status
No longer recruiting

Registration date
12/03/2012

Overall study status
Completed

Last Edited
17/12/2018

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 burden for both the affected persons and their families. It typically manifests during late childhood or early adolescence mostly in females. In many cases the disorder has a chronic course and about one patient in ten dies due to AN. Therefore, it is important to develop ways of preventing AN. Previous studies have shown that internet-based preventive interventions can help reducing such risk factors for eating disorders (ED). There are a few studies about bulimia nervosa and binge eating disorder but there are no studies for AN. and this is the aim of this research. We want to explore how many girls and adolescents are at risk for AN. Our online program E@T (Eltern als Therapeuten; German version of P@N - Parents Act Now, Stanford University School of Medicine) was developed for parents of females aged 11 to 17 at risk for AN. In 6 weekly sessions parents are educated about the danger of AN and the need to intervene early. In addition, they are encouraged to take definitive steps to intervene in case of any weight loss efforts (e.g. dieting, excessive participation in physical activities) in order to prevent the deterioration of these behaviors and/or potential medical and psychological problems. An online program can facilitate dissemination, be readily adapted and updated, provide contents 24h a day, permit interactivity and eventually reduce costs.

Who can participate?
Every female aged 11 to 17 years can take part in the study when she has a combination of selected risk factors (e.g. excessive participation in physical activities, strong weight and shape concerns) and/or early symptoms of AN (e.g. lower than 90% of her ideal body weight, amenorrhea).

What does the study involve?
We follow a two-step procedure. At first we are screening young females at risk through questionnaires at schools. Then the parents get the opportunity to take part in an internet-based prevention program. When a girl or adolescent fulfills the inclusion criteria her family is randomly allocated to the intervention group or the control group. In the intervention group, a short internet-based prevention program is offered. The intervention consists of an online program for parents with 6 sessions over 6 weeks moderated by eating disorder experts (qualified psychologists). At the end of the program there is a post interview as well as 4 follow-up interviews every 6 months. The control group does not get access to the online program.

What are the possible benefits and risks of participating?
If parents are included in the intervention group they are educated on the danger of AN and encouraged to take steps against weight loss efforts (dieting, diet pills, excessive exercise) in order to prevent the deterioration of these behaviors and/or medical and psychological problems. In the follow-up interviews parents that are included in the control group get information about their daughter's risk status. There are no known risks or side effects for participants.

Where is the study run from?
The study is run from Dresden, Germany and recruitment is done in Saxony (Eastern German state where Dresden is located), but because our intervention is internet-based and interviews can take place over the phone, participants from the whole of Germany can take part.

When is the study starting and how long is it expected to run for?
The study started in February 2010 and recruitment will continue until December 2012.

Who is funding the study?
The study is funded by the Swiss Anorexia Nervosa Fundation (SANS).

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

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Early detection and intervention of anorexia nervosa in adolescent girls: a randomized controlled trial comparing a family-oriented, internet-based intervention with a control group without intervention

Study objectives
P@N - Parents Act Now [German: E@T - Eltern als Therapeuten].

The intervention should normalize weight (Ideal Body Weight (IBW)) and reduce the targeted potent risk factors and retrospective correlates Eating Disorder Examination (EDE) weight and shape concerns, EDE restraint, Eating Disorder Inventory (EDI) drive for thinness, EDI body dissatisfaction, driven exercise, perfectionism, self-esteem and perfectionism short term (post-treatment) and long term (follow-up).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, Faculty of Medicine Carl Gustav Carus, Technical University of Dresden [Technische Universität Dresden], 07/06/2010, ref: EK172052010

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Anorexia nervosa

Interventions
Randomized controlled trial comparing a 6-week intervention group to a monitored, non-intervention control group with outcome comparison at post-treatment and every 6 months E@T (Eltern als Therapeuten; German version of P@N - Parents Act Now, Stanford Medical School).

The intervention consists of an online program for parents of adolescent daughters with 6 sessions over 6 weeks moderated by eating disorder experts (e.g. diploma-level psychologists). Parents are educated on the danger of AN and the need to intervene to prevent this outcome. In addition, parents are encouraged to take definitive steps to intervene with any weight loss efforts (dieting, diet pills, over exercise) in order to prevent the elaboration of these behaviors with an attendant escalation in medical and psychological problems. Additional features are an online discussion group, two phone calls to enable individualized feedback on the child's problems with eating, weight and shape, and referral to other resources (self-help-guide, Lock & Le Grange, 2006); in- or outpatient treatment) if necessary.
We favor an online program because such programs increase ease of dissemination, can be readily adapted and updated, provide contents 24 hours/day, permit interactivity and other multimedia functions (e.g. videos) to make the program more attractive to consumers, generate an automatic data base on adherence, and eventually reduce cost.

The outcomes will be compared at post-treatment and every 6 months for 2 years (follow-up).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
AN symptoms:
1. Weight normalization - chnages in BMI
2. Weight and shape concerns, eating concerns, restraint (restricitive eating): Eating Disorder Examination (EDE, interview)

Secondary outcome measures
1. Risk status (as described in inclusion criteria, questionnaire)
2. Full or partial AN diagnoses: Eating Disorder Examination (EDE, interview)
3. Drive for thinness, body dissatisfaction: Eating Disorder Inventory 2 (EDI-2, questionnaire)
4. Self-esteem: Rosenberg Self-Esteem Scale (RSE, questionnaire)
5. Depression: Beck's Depression Inventory II (BDI-II, questionnaire)
6. Perfectionism: Frost Multidimensional Perfectionism Scale (MPS-F, questionnaire)
7. Social adjustment: Social Adjustment Scale (SAS, German version: Fragebogen zur sozialen Integration, FSI, questionnaire)

Overall study start date
01/02/2010

Completion date
01/02/2014

Eligibility

Key inclusion criteria
1. Female
2. Age 11 - 17 years
3. Informed consent by adolescent girl and their parents

4. Being at high risk for anorexia nervosa (AN), meaning to fulfill the combination AB or BC or ABC of the following variables:
A. High weight and shape concerns
B. Low weight (below 90% IBW) or normal weight (90-115% IBW) but weight loss of at least 5% in the past 6 months or >115% IBW but weight loss of at least 10% in the past 6 months
C. Presence of at least one the following risk factors: High-level perfectionism, family history of ED, driven exercise (excessive engagement in physical activities) or primary or secondary amenorrhea

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
17 Years

Sex
Female

Target number of participants
100 high risk subjects

Key exclusion criteria
1. Current full eating disorder diagnosis
2. Treatment for ED within the past six months
3. Acute suicidal ideation
4. Drug or alcohol abuse or dependence

Date of first enrolment
01/02/2010

Date of final enrolment
01/12/2012

Locations

Countries of recruitment
Germany

Study participating centre
Technische Universität Dresden
Dresden
Germany
01187

Sponsor information

Organisation
Swiss Anorexia Nervosa Foundation (Switzerland)

Sponsor details
Klünenfeldstrasse 22
Birsfelden
Switzerland
CH - 4127

Sponsor type
Government

Website
http://www.anorexia-nervosa.ch/

ROR
https://ror.org/00kb3m272

Funder(s)

Funder type
Government

Funder Name
Swiss Anorexia Nervosa Foundation (Switzerland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	14/12/2018		Yes	No