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Treatment of compulsive exercise in anorexia nervosa

Submission date	Recruitment status	[ ] Prospectively registered
23/03/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/07/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/08/2023	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Anorexia nervosa is an eating disorder where a person keeps their body weight as low as possible. A frequent and characteristic, yet insufficiently studied symptom that can be observed in 31-81% of patients is compulsive exercise. Compulsive exercise is associated with lower short-term response to treatment and poorer long-term outcome. Despite this, no interventions specifically targeting compulsive exercise behavior have been tested so far. An 8-session, manualized group intervention has been developed to promote healthy exercise behavior by both reducing the compulsive quality and excessive quantity of the patients' exercise behavior. After a small study showed promising results, the aim of this study is to test how well this treatment works as add-on to regular inpatient treatment.

Who can participate?
Female patients aged 14-45 with anorexia nervosa and compulsive exercise

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the control group receive routine inpatient treatment. Participants in the intervention group receive the new group intervention as add-on to regular inpatient treatment. This comprises eight sessions (of 100 minutes) and is delivered by a clinical psychologist and a sports therapist. All participants' compulsive exercise behaviour is assessed at admission, before and after the intervention, at discharge and at 6 months after discharge..

What are the possible benefits and risks of participating?
Possible benefits of participating include a stronger reduction of compulsive exercise behavior. The possible risks are not known.

Where is the study run from?
Schön Klinik Roseneck (Germany)

When is the study starting and how long is it expected to run for?
May 2013 to May 2016

Who is funding the study?
Swiss Anorexia Nervosa Foundation

Who is the main contact:?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Project no. 26-13 at Swiss Anorexia Nervosa Foundation

Study information

Scientific Title
Efficacy of a specialized group intervention for compulsive exercise in inpatients with anorexia nervosa: a randomized controlled trial

Study objectives
Compared to routine inpatient treatment (treatment as usual), additional participation in the new manualized group intervention "Healthy exercise behavior" (HEB) will result in significantly lower scores in the Commitment to Exercise Scale (CES) at the end of the group (T2).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Ludwig Maximilian University Munich, Germany, 08/05/2013, project number: 060-13

Study design
Single-center interventional randomized superiority trial with two parallel treatment arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Anorexia nervosa

Interventions
Randomisation was conducted using randomizer.org (Urbaniak & Plous, 2013). Participants will be randomized to one of two treatment arms:

1. Inpatient routine treatment (treatment as usual=TAU): The specialized inpatient treatment for patients with AN consists of a multimodal cognitive-behavioral approach and intense psychiatric and internistic treatment. All patients receive individual treatment twice per week, a non-specific problem-solving group treatment three times per week and take part in a manualized, symptom-oriented group intervention for eating disorder patients. Furthermore, all AN patients participate in supervised meals three times per day, meal preparation classes, social skills training and art therapy. Patients can also take part in exercise therapy depending on their weight and physical condition. All underweight patients are required to gain at least 700g per week.

2. TAU + participation in the specific group intervention "Healthy exercise behavior" (HEB): The HEB intervention is manual-based, comprises eight sessions (of 100 minutes) and is delivered by a clinical psychologist and a sports therapist. During each session, cognitive-behavioral as well as exercise-based treatment elements complement each other. Between the sessions, patients are required to complete homework tasks. Group sessions are supplemented by individual graded exposure and response prevention tasks concerning exercise behavior guided by one of the therapists.

Measurements are taken at five timepoints: at admission (T0; baseline), before the start of HEB (T1), after the end of HEB (T2), at discharge (T3) and at 6-months after discharge (T4; follow-up).

Intervention Type
Behavioural

Primary outcome measure
Compulsive exercise behavior, measured using the Commitment to Exercise Scale (CES) at admission (T0; baseline), before the start of HEB (T1), after the end of HEB (T2), at discharge (T3) and at 6-months after discharge (T4; follow-up)

Secondary outcome measures
1. Compulsive exercise behavior, measured using the Compulsive Exercise Test
2. Eating disorder psychopathology, measured using the Eating Disorder Inventory-2 and Eating Disorder Examination-Questionnaire
3. General psychopathology, measured using the Beck Depression Inventory-II; Brief Severity Index-18; Obsessive Compulsive Inventory-Revised

4. Emotion regulation skills, measured using the Difficulties in Emotion Regulation Skills Questionnaire
5. BMI, measured by trained and masked nursing staff as part of routine treatment

All outcomes measured after admission (T0; baseline), before the start of HEB (T1), after the end of HEB (T2), before discharge (T3) and at 6-months after discharge (T4; follow-up)

Overall study start date
01/05/2013

Completion date
08/05/2016

Eligibility

Key inclusion criteria
1. Female gender
2. DSM-IV diagnosis of AN (DSM-IV 307.1) or atypical AN /EDNOS (DSM-IV 307.50)
3. Presence of compulsive exercise, which was defined based on modified DSM-IV criteria for OCD
3. Age: 14-45 years

Participant type(s)
Patient

Age group
Mixed

Sex
Female

Target number of participants
Minimum of 168 participants

Key exclusion criteria
1. Body-mass-index (BMI) < 13 kg/m² at the beginning of the Intervention
2. Drug, alcohol or other substance abuse
3. Presence of additional severe psychiatric or neurological disease and suicidality
4. Concurrent treatment for OCD
5. Severe somatic complications, that would prohibit attending a 100 minute group session and /or light to moderate supervised exercise
6. Marked cognitive impairment due to underweight

Date of first enrolment
01/10/2013

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

Website
http://www.schoen-kliniken.de/ptp/kkh/ros/

ROR
https://ror.org/007ztdc30

Funder(s)

Funder type
Charity

Funder Name
Swiss Anorexia Nervosa Foundation

Results and Publications

Publication and dissemination plan
The trialists intend to submit the first paper for publication in June 2017

Intention to publish date
01/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Ulrich Voderholzer (UVoderholzer@schoen-kliniken.de)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article	feasibility and preliminary outcomes	11/09/2018	30/08/2023	Yes	No