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Evaluation of a new psychological treatment for anorectic eating disorder

Submission date
12/04/2017

Recruitment status
No longer recruiting

Registration date
18/05/2017

Overall study status
Completed

Last Edited
14/06/2023

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 serious eating disorder in which people keep their body weight low by dieting, vomiting, using laxatives or excessively exercising. It affects men and women of all ages, but is most common in young women. It is a serious condition, with a higher death rate than any other mental health disorder. There is currently no evidence-based treatment available to anorexic patients, and treatments currently on offer have been criticised for failing to address the underlying problem of the disorder. Radically open dialectical behavior therapy (RO-DBT) is a new treatment which has been developed to target emotional overcontrol (excessive need to control), a suggested underlying cause of the development and maintenance of AN and other restrictive eating disorders (where a person restricts what they eat). Initial studies show promising results however more research is needed to evaluate whether the treatment is effective. The aim of this study is to evaluate the effectiveness of RO-DBT in the treatment of AN and other restrictive eating disorders.

Who can participate?
Adults who are suffering from anorexia nervosa who are overcontrolling with themselves.

What does the study involve?
All participants take part in the 40-week long RO-DBT. This involves individual therapy, which is made up of six weeks focusing on eating disorder symptoms relevant to the patient (e.g. regularly and sufficient eating) and 30 weeks of sessions which focus themes (e.g. rigidity and distance in relation to others) as well as continuously working with relevant eating disorder specific treatments. Skills training also takes place in groups over 29 weeks and aims to improve skills in radical openness (e.g. flexibility), relationships, emotional awareness and regulation, mindfulness and distress tolerance. Participants are assessed before and after the treatment, as well as at the start of each session using questionnaires to assess their eating disorder symptoms and wellbeing as well as having their weight recorded.

What are the possible benefits and risks of participating?
It the treatment is successful the participants will benefit from learning skills which could help them recover from their eating disorder. There is a risk that some participants could feel a pressure to take part, since they are asked about participation by their clinical contact. They will

all get clear information about that participation or not will not influence the care they will receive. Those who decline participation or drop-out from the study will be offered treatment as usual.

Where is the study run from?
Uppsala University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to December 2020

Who is funding the study?
1. Uppsala University Hospital (Sweden)
2. Uppsala University (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2014/252

Study information

Scientific Title
Radically open dialectical behavior therapy (RO-DBT) for restrictive eating disorders

Study objectives
Primary hypotheses:
1. After treatment with RO DBT the patients will restore their weight and reduce eating disorder symptoms measured with the Eating Disorder Symptom List (EDSL) and Eating Disorders Examination Questionnaire (EDE-Q)
2. In a design with multiple base lines, positive changes in eating disorder symptoms measured with EDSL and weight will be observable six weeks after introduction of interventions directed towards weight regain

Secondary hypotheses:
1. Patients quality of life measured with Brunnsviken brief quality of life scale (BBQ), level of function measured with Clinical impairment questionnaire (CIA) and positive feelings in social situations (SSPS) will increase during treatment
2. Patients will reduce maladaptive behaviors related to their overcontrolled personality style in the areas in which the treatment is directed at: i.e rigidity, aloof and distant relationships, risk avoidance, emotional inhibition, and envy/bitterness
3. Changes in maladaptive overcontrolled behaviors will be observable within four weeks after the intervention targeting the behavior is introduced

Ethics approval required
Old ethics approval format

Ethics approval(s)
Uppsala Ethical Review Board, 25/06/2014, ref: 2014/252

Study design
Non randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anorexia nervosa or eating disorder NOS primarily restrictive

Interventions
All participants take part in the radically open-dialectical behavior therapy (RO-DBT). This involves a 40 week program given both as individual and as skills training in group simultaneously.

Individual therapy consists of a six week long engagement phase (10 sessions) with primary focus on eating disorder symptoms relevant to the patient (e.g. regularly and sufficient eating) and a 30 week long phase (30 sessions) focusing on OC-relevant themes (e.g. rigidity and distance in relation to others) as well as continuously working with relevant eating disorder specific interventions.

Skills training is introduced after the engagement phase simultaneously with phase 2 described above. Skills training runs for 29 weeks and aims at improving skills in radical openness (e.g. flexibility), relationships, emotional awareness and regulation, mindfulness and distress tolerance.

A follow-up will be performed at six months.

Intervention Type
Behavioural

Primary outcome(s)
1. Weight is measured weekly during baseline by the study leader Martina Isaksson and by the individual therapist at the beginning of every session and at six months follow-up
2. Eating behaviors are measured weekly by the participant on a Likert scale reporting on four questions about regular eating, sufficient eating, flexible and variable eating
3. Eating disorder symptoms is reported weekly by the participants using the eating disorder symptom list (EDSL) and collected during baseline by the study leader Martina Isaksson and by the individual therapist at the beginning of every session and at six months follow-up
4. Eating disorder symptoms is reported by the participants using the eating disorder examination questionnaire (EDE-Q) at pre and post treatment and at six months follow-up

Key secondary outcome(s))
1. Quality of life is reported by the participants measured using the Brunnsviken brief quality of life scale (BBQ) at pre and post treatment and at six months follow-up
2.Clinical impairment due to eating disorder is measured using the Clinical impairment questionnaire (CIA) at pre and post treatment and at six months follow-up
3. Quality in relationships is measured using the Social safeness an pleasure scale (SSPS) at pre and post treatment and at six months follow-up
4. Behaviors of overcontrol are assessed weekly using visual analogues scales (VAS) during baseline by the study leader Martina Isaksson and by the individual therapist at the beginning of every session and at six months follow-up

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Anorexia nervosa or EDNOS-R
2. Overcontrolled personality style
3. BMI > 16
4. Aged 18 years and over

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Total final enrolment
13

Key exclusion criteria
1. In immediate need of treatment for other psychiatric or somatic condition
2. In need of more intensive treatment for eating disorder e.g. inpatient care
3. Participated in any psychological treatment for ED during the last three months
4. Insufficient cognitive capacity or insufficient knowledge in the Swedish language

Date of first enrolment
10/10/2016

Date of final enrolment
01/06/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Hospital
Entrance 10
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Uppsala University Hospital (Akademiska Sjukhuset)

Alternative Name(s)
Uppsala University Hospital

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
Uppsala University (Uppsala Universitet)

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the high chance of identifying participants. The datasets will be stored at Uppsala University.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/01/2021	24/08/2021	Yes	No