

# Evaluation of a new psychological treatment for anorectic eating disorder

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 14/06/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> 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?

If 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?

Dr Mia Ramklint

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Non randomised study

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

## **Secondary outcome measures**

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 and 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

## **Overall study start date**

01/01/2014

## **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

50

**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

## Sponsor details

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## Sponsor type

University/education

## Website

<https://www.uu.se/om-uu/kontakta-oss/>

## 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

**Publication and dissemination plan**

The results will be published in scientific papers.

**Intention to publish date**

01/06/2021

**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?
<a href="#">Results article</a>		12/01/2021	24/08/2021	Yes	No