

Long-term evaluation of acceptance and commitment therapy for adults with anorexia nervosa

Submission date 08/06/2016	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
Registration date 08/06/2016	Overall study status Completed	
Last Edited 01/08/2016	Condition category Mental and Behavioural Disorders	

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. AN affects the whole body, and can lead to serious mental health issues, such as depression and problems with cognitive (thinking, learning and memory), as well as damage to major organs such as the heart and kidneys. Treatment for AN usually involves a combination of different kinds of talking therapies and medications which reduce feelings of anxiety or depression. Currently, no psychological or drug treatment has been identified as superior and many patients often become anorexic again in the long-term (relapse). Acceptance and Commitment Therapy (ACT) is a type of talking therapy which uses that uses acceptance and mindfulness (a way of observing experiences in the present moment, without judgment) strategies, together with commitment and behaviour change strategies, to help a person to deal with difficult situations they may face. The aim of this study is to find out whether ACT can help to reduce relapse and increase recovery compared to standard treatment.

Who can participate?

Adults with AN who have completed 9-12 weeks of daycare treatment at the eating disorder unit of Uppsala University Hospital.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive treatment as usual. This involves being given support in maintaining regular and sufficient eating as well as to restore weight by members of the hospital team. The total length of this treatment is 19 weeks. Participants in the second group take part in ACT. This involves taking part in hour-long face-to-face sessions once a week for 19 weeks. These participants are not allowed to receive any additional therapy during their treatment, but are able to attend daycare at the eating disorder unit. At the start of the study, after treatment (19 week), and then six, 12, 18, 24 months and five years later, participants have their BMI measured to find out if they are able to reach and maintain a healthy weight, as well as completing a number of questionnaires about their mental health.

What are the possible benefits and risks of participating?

Participants who take part in the ACT may benefit from improved mental and physical health in comparison to those who receive treatment as usual. There are no notable risks involved with taking part in the study.

Where is the study run from?

Uppsala University Hospital (Sweden)

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

April 2003 to December 2012

Who is funding the study?

1. Swedish Research Council (Sweden)
2. Söderström-Königska Foundation (Sweden)
3. Märta and Nicke Nasvell Foundation (Sweden)

Who is the main contact?

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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

Study information

Scientific Title

A randomised trial of Acceptance and Commitment Therapy for Anorexia Nervosa after daycare treatment, including five-year follow-up

Study objectives

After 9-12 weeks of daycare, Acceptance and Commitment Therapy will reduce relapse and increase recovery compared with treatment as usual.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional ethical committee in Uppsala (Sweden), 22/12/2013, ref: Ups 03-519

Study design

Single-centre randomised controlled trial with longitudinal follow up

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 below to request a patient information sheet.

Health condition(s) or problem(s) studied

Anorexia nervosa

Interventions

At completion of daycare (9-12 weeks), patients were invited to participate in the study. Those who consented to participate were assessed (baseline, pre-treatment). After baseline assessments were completed participants were randomized to either ACT or to Treatment as usual (TAU). The head psychologist at the eating disorder unit was given sealed prepared envelopes that revealed the result of the randomization for each participant. The contact person of this registry attained the randomization sequence at www.randomizer.org (1:1 ratio). Each envelope was marked with a participant number and contained only the result of the randomization (i.e. ACT or TAU). Before the inclusion started the head psychologist received these envelopes.

Intervention group: The Acceptance and commitment therapy (ACT) consisted of 19 weekly face to face psychotherapy sessions, 1 hour each. The treatment is based on principles of Acceptance and Commitment Therapy (ACT) in which the following processes are included; Being present (increasing the ability to make contact with the present moment); Self-as-context (increasing the ability to take perspective on internal events, as well as on events and situations in the past, present and thoughts of the future); Defusion (increase the ability to identify thoughts that have an automatic impact and importance and increase the ability to reduce the literal meaning so that thoughts are experienced as thoughts), Acceptance (increase the ability to embrace inner experiences as they occur), Values (increase the awareness of what constitute meaning, vitality, and/or how one wants to be and act in different areas of life, goals are tightly connected to values), and Commitment (involves taking action and redirecting action towards goals that aim at the individuals values). Participants in this condition will also continue to receive care as deemed appropriate at Uppsala university hospital, i.e. they will also receive treatment as usual. Participants in the ACT treatment arm may not receive any other psychotherapy during the ACT treatment period.

Control group: All patients will receive usual medical care as deemed appropriate by their treating clinicians at the Uppsala university hospital. The TAU condition aimed to support the patients in maintaining regular and sufficient eating as well as to restore weight. Most commonly this was provided by a nurse, but they could also see a physiotherapist, a dietician or a psychologist. Treatment could also target co-morbid disorders. The TAU condition involved any type of further treatment that was available for and chosen by the patients; hence, there was no specific treatment provider. The treatment as usual period was identical with the ACT treatment period, i.e 19 weeks.

Participants are followed up post-treatment (19 weeks) and then 6, 12, 18, 24 months and 5 years post-treatment.

Intervention Type

Behavioural

Primary outcome measure

1. Body Mass Index (kg/m^2) is calculated from weight and height measurements at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment
2. Eating disorder examination questionnaire (EDE-Q) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment

Secondary outcome measures

1. Depressive symptomatology is measured using The Montgomery Åsberg Depression Rating Scale (MADRS-S) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
2. Satisfaction with different areas of life is measured using the Quality of Life Inventory (QOLI) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
3. Perceived social support from friends and from family is measured using the Perceived Social Support (PSS) questionnaire at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment
4. Current psychological symptoms are measured using six sub-scales of the Symptom Check List (SCL-90) - Somatization, Obsessive-Compulsive, Interpersonal sensitivity, Anxiety, Anger-Hostility and Phobic Anxiety, from which the Global Severity Index was estimated at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.

5. Self-esteem is measured using the Rosenberg Self-Esteem Scale (RSE) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
6. Concerns about body shape are measured using the Body Shape Questionnaire (BSQ) at baseline (pre-treatment), post-treatment 19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
7. Thoughts and actions used to cope with a specific stressor are measured using the Ways of Coping Questionnaire (WCQ) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
8. Attitudes, feelings and behaviors associated with eating disorders are measured using the subscales Drive for thinness, Bulimia, Body satisfaction, Ineffectiveness, Interpersonal distrust and Interoceptive awareness from the Eating Disorder Inventory-2 (EDI) at baseline (pre-treatment), post-treatment (19 weeks), 6, 12, 18, 24 months and 5 years post-treatment.
9. Impact of eating disorders on psychosocial functioning is measured using the Clinical Impairment Assessment scale (CIA) at 5 years
10. Use of health care services is measured using patients' psychiatric records from pre to post ACT / TAU, and from post through 12 months follow-up

Overall study start date

01/04/2003

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. 18 years or older
2. AN or partial AN (EDNOS) at intake to daycare treatment
3. 9-12 weeks of completed daycare at the eating disorder unit

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

The target for recruitment was 120 participants

Key exclusion criteria

Not meeting inclusion criteria

Date of first enrolment

01/08/2005

Date of final enrolment

29/01/2009

Locations

Countries of recruitment

Sweden

Study participating centre**Uppsala University Hospital**

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Funder(s)

Funder type

Research council

Funder Name

Vetenskapsrådet

Alternative Name(s)

Swedish Research Council, VR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Söderström-Königska Foundation

Funder Name

Märta and Nicke Nasvell Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2016

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/07/2016		Yes	No