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

Submission date
08/06/2016

Recruitment status
No longer recruiting

Registration date
08/06/2016

Overall study status
Completed

Last Edited
01/08/2016

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. 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 taking 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?
Dr Thomas Parling
thomas.parling@psyk.uu.se

Contact information

Type(s)
Scientific

Contact name
Dr Thomas Parling

ORCID ID
https://orcid.org/0000-0002-6159-598X

Contact details
Uppsala university
Campus Blåsenhus
von Kraemers allé 1A och 1C
Uppsala
Sweden
751 42
+46 (0)70 2058007
thomas.parling@psyk.uu.se

Additional identifiers

Protocol serial number
-

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

Primary study design
Interventional

Study design
Single-centre randomised controlled trial with longitudinal follow up

Study type(s)
Treatment

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(s)
1. Body Mass Index (kg/m*m) 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

Key secondary outcome(s)
1. Depressive sympotomology 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) questionnaireat 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 meaured 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 sub-scales 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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
VO Affektiva sjukdomar, ingång 10
751 85 Uppsala
Uppsala
Sweden
751 85

Sponsor information

Organisation
Uppsala University (Sweden)

ROR
https://ror.org/048a87296

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

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