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Affect school as complementary treatment in eating disorders

Submission date	Recruitment status	[_] Prospectively registered
29/03/2018	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/10/2022	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Eating disorders are relatively common, serious psychiatric disorders that cause significant suffering for persons with eating disorders and their families and friends. Eating disorder diagnoses include anorexia nervosa (AN), bulimia nervosa (BN), and related eating disorders. The condition is considered hard to treat. Persons with an eating disorder inhibit or repress emotions, have a poorer emotional awareness, and tend to have larger problems coping with emotions compared to healthy persons. This is a problem when working towards recovery.
This study aims to evaluate the effect of adding Affect school treatment to regular eating disorder treatment at an outpatient clinic.With this intervention we aim to enhance emotional awareness and coping and therefore reach better results in the treatment of eating disorders.

Who can participate?
Patients at the AnorexiBulimiCenter (ABC) will be asked to participate in this study. The ABC is a public, youth/adult, integrated psychiatric outpatient clinic situated in southern Sweden. Patients with all kinds of eating disorders are treated at the clinic. Participants will be between 18-60 years old. Most of the patients are female (about 2% are men), but all patients at the clinic who has an eating disorder diagnosis, speaks Swedish, has a Body Mass Index over 15, who is not suicidal or having an ongoing psychosis, and who is not in an acute starvation will be asked to participate in the study.

What does the study involve?
Participants will be randomly allocated into two groups; an Affect school group and a control group. Participants in both groups will continue their regular treatment at the clinic (for example psychotherapy, physiotherapy, day care). Participation is voluntary and the evaluation of the intervention will be performed using self-assessment scales on eating disorder symptoms and emotion coping, together with eating disorder diagnoses before and twelve months after the intervention. Some of the patients (randomly chosen) will participate in an interview about the Affect school after their participation in the group treatment.
The Affect school is an eight session group treatment that covers basic emotions like joy, anger, interest, fear, disgust, dissmell and shame. The weekly sessions last for two hours and contain education on emotions together with manual based group discussions.

What are the possible benefits and risks of participating?
There will be no benefit to those who are drawn to the control group. We think there will be benefits for participants in the intervention group since the intervention may enhance participants emotional awareness which is expected to enhance the results of their regular treatment as well. We also think that sharing experiences with other patients is beneficial. Regarding risks for impairment of participants' psychiatric condition, the staff at the clinic is well educated and experienced and performs regular evaluations of the patients (including the participants). There is a risk that by attending in the project the participants will feel that it is a waste of their time or that they will experience the meetings negatively. There is also a risk that participants in the control group will be disappointed when they do not get the possibility to attend the Affect school.

Where is the study run from?
ABC clinic, Kalmar County Council (Sweden)

When is the study starting and how long is it expected to run for?
October 2017 to December 2020.

Who is funding the study?
1.Division of Psychiatry, Kalmar County Council (Sweden)
2.Fredrik och Ingrid Thurings Stiftelse (Sweden)

Who is the main contact?
Dr Suzanne Petersson
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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
531-31

Study information

Scientific Title
Affect school as complementary treatment in eating disorders:
A randomized controlled study

Study objectives
By adding an 8-week manual based Affect school intervention to the usual eating disorder treatment, patients are expected to be more aware of how to manage emotions and thus reduce their eating disorder symptoms (measured with Eating Disorder Examination Questionnaire, Toronto Alexythymia Scale-20, Deficits in Emotion Regulation Scale, and Body Mass Index).

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the approved by the regional ethical review board of Linköping University, Faculty of Medicine, 13/02/2018, 2017/531-31

Study design
A randomized controlled study. After informed consent has been signed, baseline measures are performed, after this the participants are randomised to either the intervention group together with their usual treatment or to TAU solely.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Eating Disorders

Interventions
Block-randomisation is performed by an independent researcher who is not a part of the project. Half of the participants will be randomized into the intervention Group, the Affect school, and keep their usual treatment at the clinic, and half of the participants will keep their treatment but

will not receive the Affect school intervention. The Affect school is a group treatment with education and discussions on emotions. The treatment is based on a manual and consists of eight sessions during eight weeks (two hours per session).

Both treatment arms will be followed up directly after the end of the intervention, then after 6 and 12 months respectively. As there will be several rounds of the treatment (each lasting 8 weeks) the follow ups will be undertaken according this pattern until the last group (and control group) have done their 12 months follow up.

Intervention Type
Other

Primary outcome measure
1.Eating disorder symptoms using the Eating Disorder Examination Questionnaire (EDE Q),which is a self-assessment scale, symptoms are measured at baseline, after the intervention, 6 and 12 months after the end of the intervention.
2. Difficulties in Emotion Regulation Scale, brief version (DERS) with a self-assessment scale called Difficulties in Emotion Regulation Scale (DERS) at baseline, at the end of the intervention, 6 and 12 months after the end of the intervention
3. Alexithymia with the self-assessment scale Toronto Alemithymia Scale-20 (TAS-20) at baseline, after the intervention, 6 and 12 months after the end of the intervention.

The same measures and time intervals apply to the intervention and the control groups.

Secondary outcome measures
1. Body Mass Index (BMI) at the start of the intervention and after 12 months.
2. Eating disorder diagnoses at baseline, at 6 and 12 months after the end of the intervention

The same measures and time intervals apply to the intervention and the control groups.

Overall study start date
01/10/2017

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. Eating disorder diagnosis
2. Swedish as spoken language
3. Aged ≥18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
Two arms with 25-30 patients in each arm. Target number for power is 21 patients in each arm.

Total final enrolment
40

Key exclusion criteria
1. BMI <15 kg/m2
2. Acute state of starvation
3. Psychosis
4. Acute high level of suicidality

Date of first enrolment
01/03/2018

Date of final enrolment
30/04/2020

Locations

Countries of recruitment
Sweden

Study participating centre
AnorexiBulimiCenter
Kaggensgatan 42
Kalmar
Sweden
S-39332

Sponsor information

Organisation
Regional Council in Kalmar County

Sponsor details
Division of Psychiatry
Box 601

Kalmar
Sweden
S-391 26

Sponsor type
Hospital/treatment centre

Website
http://www.ltkalmar.se/

ROR
https://ror.org/01q8h4282

Organisation
Fredrik och Ingrid Thurings stiftelse

Sponsor details
c/o SEB
Private Banking, Stiftelser ST S3
Att: Maria Liljendahl
Stockholm
Sweden
S-106 40 Stockholm

Sponsor type
Charity

Funder(s)

Funder type
Not defined

Funder Name
Fredrik och Ingrid Thurings Stiftelse, Sweden

Funder Name
Kalmar County Council

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/03/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	interview study	17/02/2021	21/05/2021	Yes	No
Basic results		17/05/2022	17/05/2022	No	No
Results article		30/05/2022	22/08/2022	Yes	No
Results article		28/07/2022	22/08/2022	Yes	No
Protocol file		22/09/2022	06/10/2022	No	No