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Taking the LEAP: an evaluation of the compuLsive Exercise Activity Program (LEAP) in patients with eating disorders

Submission date
18/12/2019

Recruitment status
No longer recruiting

Registration date
25/03/2020

Overall study status
Completed

Last Edited
02/10/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Eating disorders (EDs) are severe and often long-term psychiatric illnesses, featuring high rates of both medical and psychiatric comorbidity and a pronounced risk of death. Lifetime prevalence (age 15-60) of EDs in Sweden today is about 3.5%. A significant proportion of ED patients (25-50% depending on ED diagnosis) are still ill 10 years following treatment intake. Compulsive exercise (CE) is a common and prominent symptom in various ED presentations and in both genders. CE is often used to control body weight and shape, compensate for food intake, and/or to regulate negative affect. It is characterised by rigidity and an inability to stop exercising despite negative consequences. CE has been linked to more severe ED pathology, risk of suicide and lower remission rates. About 50% of Swedish ED patients, irrespective of diagnosis and gender, report CE, yet to date there are no treatments targeting CE in Swedish specialist ED care. There are, however, promising findings for a targeted cognitive behavioural therapy (CBT) intervention developed in the UK: the CompuLsive Exercise Activity Program (LEAP), which aims to promote functional beliefs and behaviours in relation to physical activity, and help patients regain control of their exercise behaviour. This study aims to evaluate its efficacy for ED patients in Swedish specialist care by comparing a group of patients with EDs who receive standard treatment with a group of patients who receive standard treatment plus LEAP.

Who can participate?
Male and female patients, aged 18 and over, with an eating disorder with compulsive exercise, entering outpatient care at a specialised ED treatment unit

What does the study involve?
Participants are randomly allocated to receive either standard treatment or standard treatment plus LEAP. LEAP is a cognitive behavioural group treatment that is supposed to be given as an addition to treatment as usual to patients suffering from eating disorders with compulsive exercise as a symptom. LEAP is delivered in 1 individual session and 8 group sessions over 4 consecutive weeks. A group consists of 4-8 individuals. The aim of LEAP is to equip patients with knowledge and skills that enable them to challenge maladaptive beliefs and behaviours, regain control of their exercise behaviour, and participate in exercise that is appropriate in relation to

age, goals, and health status. The control group receive treatment as usual (a medical contact, a therapeutic contact - most commonly CBT-E, possibly eating support, etc - this is individualised to suit each patient's needs).

What are the possible benefits and risks of participating?
The possible benefits include returning to a more healthy way of exercising and experiencing less compulsivity and rigidity in relation to exercise. The risk is that this intervention is not all that helpful and thus patients invest time and energy doing something that does not really help. On the other hand, extra time with a therapist/psychologist working on one of their core symptoms may probably at least not do any harm.

Where is the study run from?
1. Anorexi-bulimimottagningen, Sahlgrenska Universitetssjukhuset, Göteborg (Sweden)
2. Ätstörningsenheten Eriksbergsgården, Örebro (Sweden)
3. Ätstörningsenheten, Akademiska Sjukhuset, Uppsala (Sweden)
4. Stockholms centrum för ätstörningar, Stockholm, (Sweden)
All in collaboration with Karolinska Institute, the department of medical biostatistics and epidemiology (MEB).

When is the study starting and how long is it expected to run for?
December 2017 to December 2025

Who is funding the study?
1. Söderström-Königska Foundation
2. ALF medicine projektmedel
3. Centre for Psychiatry Research (CPF; The Stockholm County Council)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2018/1308-31 (ethics protocol)

Study information

Scientific Title
Taking the LEAP: an effectiveness trial of the compuLsive Exercise Activity Program (LEAP) - a cognitive behavioural program specifically targeting compulsive exercise in patients with eating disorders

Acronym
LEAP

Study objectives
Primary: what are the treatment effects of LEAP on ED diagnosis, ED cognitions, CE behaviours and cognitions, BMI, emotion regulation and general psychopathology, after 3 months and at 6 month follow-up?
Secondary: are there initial factors (e.g. BMI, gender, emotion regulation, compulsivity) that predict a more favourable outcome for patients in the LEAP group?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 14/07/2021:
Approved 08/08/2018, Swedish regional board of ethics (FE 289, 171 77 Stockholm, Sweden; Tel: +46 (0)8 524 870 00 (vx); Email: kansli@stockholm.epn.se), ref: DNR: 2018/1308-31, 2020-01173, 2021-02870

Previous ethics approval:
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Study design
Two-armed parallel open-label randomized naturalistic effectiveness superiority trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Current interventions as of 14/07/2021:
Eligible patients are recruited in collaboration with eating disorder specialist treatment units. Patient consenting to participate will be assigned experimental condition by an allocating investigator (AI), using an online random number generator, stratified by site, diagnosis, and gender. The AI is the only person with access to randomisation group data.

LEAP is a cognitive behavioural group treatment that is supposed to be given as an addition to treatment as usual to patients suffering from eating disorders with compulsive exercise as a symptom. LEAP is delivered in 1 individual session and 8 group sessions over 4 consecutive weeks. A group consists of 4-8 individuals. The aim of LEAP is to equip patients with knowledge and skills that enable them to challenge maladaptive beliefs and behaviours, regain control of their exercise behaviour, and participate in exercise that is appropriate in relation to age, goals, and health status.

The control group receive treatment as usual (a medical contact, a therapeutic contact - most commonly CBT-E, possibly eating support, etc - this is individualised to suit each patient's needs).

Clinicians conducting pre- and post-assessments are blinded, and LEAP clinicians do not carry out assessments. Participants cannot be blinded to group, since LEAP deviates too much from standard ED treatment.

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Clinicians conducting pre- and post-assessments are blinded, and LEAP clinicians do not carry out assessments. Participants cannot be blinded to group, since LEAP deviates too much from standard ED treatment.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 14/07/2021:
1. Eating disorder (ED) diagnosis measured by the Eating Disorder Examination (EDE) or the Structured Eating Disorder Interview (SEDI) at baseline and 6 months
2. ED cognitions measured by the Eating Disorder Examination Questionnaire (EDEQ) at baseline, 3, and 6 months

3. Compulsive Exercise measured by the Compulsive Exercise Test (CET) at baseline, 3, and 6 months
4. Body Mass Index (BMI) at baseline, 3, and 6 months
5. The difficulties in emotion regulation scale (DERS) at baseline, 3, and 6 months

Previous primary outcome measure:
Assessed initially and at 6-month follow-up (T3). All these outcome variables, except ED diagnosis, will also be assessed at the 3-month follow-up (T2):
1. Eating disorder (ED) diagnosis measured by the Structured Eating Disorder Interview
2. ED cognitions measured by the Eating Disorder Examination Questionnaire
3. Compulsive Exercise measured by the Compulsive Exercise Test

Key secondary outcome(s))
Current secondary outcome measures as of 14/07/2021:
1. General psychopathology measured by the DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure at baseline, 3, and 6 months
2. Active Q at baseline, 3, and 6 months
3. Patient rated treatment content (to control for potential efforts geared at CE in the TAU group) at baseline and 6 months
4. Feasibility and acceptability questionnaire (patient satisfaction with LEAP, only LEAP group) at baseline and 6 months

Previous secondary outcome measures:
Assessed initially and at 6-month follow-up (T3). All these outcome variables, except ED diagnosis, will also be assessed at the 3-month follow-up (T2):
1. Body Mass Index (BMI)
2. General psychopathology measured by the DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure

Completion date
19/12/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 14/07/2021:
1. Male and female patients, ≥18 years of age
2. AN, BN or OSFED (Atypical AN, BN/Binge Eating Disorder with low frequency and/or limited duration of symptoms, and Purging Disorder)
3. Reporting CE at T1 (EDEQ item 27, see Instruments)
4. Entering outpatient care at a specialised ED treatment unit

Previous participant inclusion criteria:
1. Male and female patients, ≥18 years of age
2. AN, BN or OSFED (Atypical AN and BN/Binge Eating Disorder with low frequency and/or limited duration of symptoms)
3. Reporting CE at T1 (EDEQ item 27, see Instruments)
4. Entering outpatient care at a specialised ED treatment unit

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Inability to communicate in Swedish
2. Psychotic disorder
3. High suicide risk
4. BMI<14

Date of first enrolment
09/11/2021

Date of final enrolment
19/12/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Anorexi-bulimimottagningen, Sahlgrenska Universitetssjukhuset, Göteborg
Östra Sjukhuset, Vitaminvägen 17
Göteborg
Sweden
41650

Study participating centre
Ätstörningsenheten Eriksbergsgården, Örebro
Eriksbergsgatan 4
Örebro
Sweden
70230

Study participating centre

Ätstörningsenheten Akademiska Sjukhuset
Akademiska Sjukhuset
Uppsala
Sweden
75185

Study participating centre
StockholmsCentrum för Ätstörningar (SCÄ)
Wollmar Yxkullsgatan 27B
Stockholm
Sweden
11850

Study participating centre
Vuxenpsykiatrimottagning Ätstörning Lund
Baravägen 1
Lund
Sweden
221 85

Sponsor information

Organisation
Karolinska Institute

ROR
https://ror.org/056d84691

Organisation
Centrum för psykiatriforskning, SLSO

Funder(s)

Funder type
Charity

Funder Name
Söderström-Königska Foundation

Funder Name
ALF medicine projektmedel

Funder Name
Centre for Psychiatry Research (CPF; The Stockholm County Council)

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 as the researchers do not have ethical permission.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol	23/07/2021	26/07/2021	Yes	No
Other publications	Patients' experiences	01/10/2024	02/10/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file		20/12/2019	25/03/2020	No	No