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A lifestyle intervention to reduce cardiometabolic risk factors in individuals with obsessive-compulsive disorder

Submission date 27/10/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 06/11/2025	**Overall study status** Ongoing	
Last Edited 15/05/2026	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Obsessive-compulsive disorder (OCD) is characterized by intrusive thoughts and compulsive behaviours or rituals. OCD is time-consuming, often causes great suffering, and affects day-to-day functioning, often affecting work or studies and social relationships. Previous research has shown that, compared to the general population, people with OCD are at increased risk of developing cardiometabolic disorders, such as cardiovascular disease and type 2 diabetes. Many of those diseases can largely be prevented by changing one's lifestyle habits (e.g., increasing physical activity, eating healthier, and avoiding alcohol and smoking).
This study aims to compare a comprehensive lifestyle intervention in a group format, including educational and exercise sessions, to medical and lifestyle advice.

Who can participate?
Participants will be people aged 18 years and older who meet criteria for OCD (assessed by a psychologist at initial conversations) and have a sedentary lifestyle (they have less than 150 minutes/week of moderate or high intensity physical activity - i.e. physical activity that makes you feel a bit warm and short of breath).

What does the study involve?
Potential participants will first be asked to complete some introductory questions online to ensure that the study is suitable for them. After that, they may be contacted for a telephone interview to get more information about the study and check if they meet criteria for participation. If so, they will be booked in for an interview with a psychologist to go through questions about their mental well-being. This visit will take 1-1.5 hours. They will also undergo a health check with a nurse where blood tests, blood pressure, weight, waist circumference, and other health-related measures will be collected. Potential participants will also be asked whether they have had any previous health problems or are taking any medication. This visit is estimated to take about 1 hour. After this visit, potential participants will also be given an activity tracker, known as an accelerometer, that they will wear on their thigh for a week to measure physical activity. Participants will also be asked to fill out a number of questionnaires. Those meeting all the eligibility criteria will be included in the study.

To be able to measure the effect of the intervention that we want to test, participants will be randomly assigned to one of two different groups. One group will undergo a structured lifestyle intervention for 13 weeks, which includes an initial meeting to set individual goals and 12 group meetings (2 hours per session) consisting of lectures providing information on how lifestyle habits can be changed and physical exercise. The other group will get one individual session where they will receive feedback based on the baseline evaluation of their clinical characteristics, lifestyle habits, and cardiometabolic risks, as well as written educational information on healthy lifestyle habits based on national Swedish guidelines issued by the National Board of Health and Welfare.
For those included, assessments will be repeated after the intervention, and 3, 6, and 12 months after the end of the intervention.

What are the possible benefits and risks of participating?
Making changes to the lifestyle can be tough, and it is possible that anxiety and OCD symptoms may temporarily increase. Increasing one's physical activity can be tiring and can also cause temporary aches and fatigue. Previous research using similar lifestyle programs has shown that participating in these kinds of interventions is safe. Additionally, by participating in the study, participants will have the chance to improve their lifestyle habits, which, in turn, may contribute to improving physical health and preventing a number of somatic conditions. Moreover, participants will also be contributing to the scientific research on OCD, lifestyle habits, and physical health, which can influence how the healthcare system is organized in the future.

Where is the study run from?
The study includes a single site, which is the adult specialist clinic OCD-programmet, at Psychiatry Southwest, Karolinska University Hospital [Karolinska Universitetssjukhuset] in Stockholm. Study screenings, inclusion and follow-up assessments, and the delivery of the intervention will take place at this site. The organizations responsible for the study project are the healthcare services at Region Stockholm (SLSO) and Karolinska Institutet.

When is the study starting and how long is it expected to run for?
The study will start recruiting in November 2025. Participants in the trial will be active in the study for about 15 months (including the intervention plus one year of follow-up). We anticipate that the recruitment will take about 2 years. In total, the duration of the trial (from enrolment of first participant to last participant’s final measurement point) will be about 39 months.

Who is funding the study?
This trial is funded by several Swedish funding bodies, including:
1. Hjärt-Lungfonden (Swedish Heart and Lung Foundation)
2. Vetenskapsrådet (Swedish Research Council)
3. FORTE: Forskningsrådet för hälsa, arbetsliv och välfärd (Swedish Research Council for Health, Working Life and Welfare)
4. Region Stockholm/ALF Medicin
5. Karolinska Institutet
6. Kricastiftelsen (Krica Foundation)

Who is the main contact?
1. Sofia Asplund, study coordinator, sofia.asplund@ki.se
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3. Lorena Fernández de la Cruz, principal investigator, lorena.fernandez.de.la.cruz@ki.se

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Scientific, Principal investigator

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Additional identifiers

ClinicalTrials.gov (NCT)
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Hjärt-Lungfonden (Swedish Heart and Lung Foundation) grant number
20220899

Vetenskapsrådet (Swedish Research Council) grant number
2025-02741

Protocol serial number
2025-04734-01

Study information

Scientific Title
Efficacy and cost-effectiveness of a lifestyle intervention to reduce cardiometabolic risk factors in individuals with obsessive-compulsive disorder: A randomized controlled trial

Acronym
LIFT

Study objectives

The overall aim of this study is to evaluate the efficacy and cost-effectiveness of a lifestyle intervention to improve lifestyle habits and reduce cardiometabolic risk factors in individuals with obsessive-compulsive disorder (OCD).

The specific aims are:
1. To investigate whether the lifestyle intervention (LIFT, active intervention), compared to medical and lifestyle advice (control), is effective in increasing physical activity (objectively measured with an accelerometer)
2. To investigate the efficacy of the intervention, vs. the control, in changing cardiometabolic risk factors (lifestyle habits, cardiometabolic physiological, and laboratory measurements), mental health measures, functional impairment, and quality of life
3. To evaluate whether the lifestyle intervention, vs the control, is cost-effective from a healthcare provider perspective

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/08/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 75002, Sweden; +46 (0)104750800; registrator@etikprovning.se), ref: 2025-04734-01

Primary study design
Interventional

Study design
Superiority parallel-group randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Reduction of cardiometabolic risk factors and improvement of lifestyle habits in individuals with obsessive-compulsive disorder

Interventions
The included participants will be randomized at a 1:1 ratio to the active intervention or the control condition using randomly varying block sizes. Randomization will be conducted using an online randomization service (TENALEA), set up and monitored by a third party, the Karolinska Trial Alliance. The randomization will be implemented consecutively in TENALEA, which requires an authorized trial coordinator to provide a participant ID to generate a unique allocation certificate with participant ID, allocation, personnel ID, and time stamp. One or several researchers (according to a task delegation list) will be responsible for the enrolment of participants, randomization, and assigning participants to the groups. Participants will be informed that they will be allocated to LIFT or to a control. Assessors will be blind to the allocation group, and, at each follow-up assessment, they will remind the participants not to reveal details about their allocation.

ACTIVE INTERVENTION: LIFESTYLE INTERVENTION (LIFT):
The lifestyle intervention consists of two components: one initial individual session and 12 weekly group sessions including both education on lifestyle habits and physical exercise.
At week 1, participants will be offered one individual session with a clinical psychologist to

create a personal plan and set up goals for a change of lifestyle habits, based on the baseline evaluation of their clinical characteristics, lifestyle habits, and cardiometabolic risk. This session will be conducted via video or face-to-face at Karolinska Hospital, Huddinge and will have a duration of about 1 hour.
From week 2 to week 13, the participants will take part in 12 weekly group sessions, consisting of both education on lifestyle habits and physical exercise. Participants will receive a phone call the morning of the day of the session to assess risk and the possibility to attend and participate in the session. The groups will be conducted at OCD-programmet, Karolinska Hospital, Huddinge and will be facilitated by two psychologists with experience working with OCD. The total time for these sessions will be 1.5 to 2 hours every week, including a short break.
The education part is based on a previous lifestyle intervention evaluated for patients with cardiovascular risk without known psychiatric conditions, which was adapted for individuals with OCD and tested in our previous pilot trial (PMID: 40746134). Further adaptations have been made based on the experiences of the pilot, including results and participants' feedback. Each educational session will focus on a specific topic/lifestyle habit, alternating more informative sessions with sessions discussing how the information can be applied, taking into account specific hinders due to OCD. The sessions are designed to actively engage participants and encourage group discussions. Cognitive-behaviour therapy strategies to achieve behavioural change are incorporated throughout the intervention, such as psychoeducation, self-monitoring, goal setting, problem-solving, and maintenance of changes. The educational part will last around 1 hour each session.
The physical activity part is based on the Braining project (https://www.psykiatrisydvast.se/vard-hos-oss/oppenvard/affektiva--och-angestprogrammet/braining/). Braining consists of group exercise sessions led by mental health staff at Psychiatry Southwest, Region Stockholm. The sessions focus on aerobic exercise of medium to vigorous intensity and also include body weight strength-training exercise. Each session lasts 30 to 45 minutes. Besides taking part in the weekly exercise session exclusively for the study group, participants will have the opportunity and will be encouraged to attend more Braining sessions (already ongoing at the hospital for other patients with a range of mental disorders) in order to increase the weekly time dedicated to moderately intense physical activity.
Between-sessions homework will include, for example, daily registration of physical activity and implementing changes in the lifestyle habits discussed during each session. All homework assignments will be registered in the digital platform BASS.
After the 13 weeks of lifestyle intervention, participants will get access to a booster module in the digital platform BASS to help them maintain their behavioural changes. In this booster module, participants will be encouraged to continue to set up goals and promote changes in their lifestyle and review their progress. Further, information about common hinders to maintain changes and problem-solving strategies will be presented in this module. Online therapist support will be offered during the 3 months following the end of the intervention, but the booster module will continue to be available until the 12-month follow-up as a self-guided support tool.

CONTROL INTERVENTION: MEDICAL AND LIFESTYLE ADVICE:
Participants allocated to this arm will receive one individual session with a clinical psychologist on week 1, directly after randomization and allocation to this arm. This session will be conducted via video or face-to-face at Karolinska Hospital, Huddinge and will have a duration of about 1 hour. During this session, participants will receive feedback based on the baseline evaluation of their clinical characteristics, lifestyle habits, and cardiometabolic risk. Additionally, they will receive written educational information on healthy lifestyle habits based on national Swedish guidelines issued by the National Board of Health and Welfare. The recommendations include

engaging in regular physical activity, dietary guidelines based on Nordic Nutrition Recommendations, and advice to reduce alcohol consumption and quit tobacco use. At week 6, participants will be contacted on the phone for a brief individual follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome as of 15/05/2026:
Physical activity, measured with an accelerometer as change in steps/day from baseline to post-intervention. Participants will be asked to wear an accelerometer (activPAL™) 24 hours/day for seven consecutive days at each assessment point. The device is placed on the thigh. Data will be considered valid if wear time is ≥10 hours/day for at least 4 days, including at least one weekend day.

Previous primary outcome:
Physical activity, measured as change in steps/day with an accelerometer at post-intervention. Participants will be asked to wear an accelerometer (activPAL™) 24 hours/day for seven consecutive days at each assessment point. The device is placed on the thigh. Data will be considered valid if wear time is ≥10 hours/day for at least 4 days, including at least one weekend day.

Key secondary outcome(s)
Current secondary outcomes as of 15/05/2026:
All secondary outcome measures will be collected at baseline, post-intervention (primary endpoint), and 3, 6, and 12 months after the primary endpoint, unless otherwise specified.

LIFESTYLE HABITS:
1. Physical activity and activity level/sedentary behaviour will be evaluated using the following measures:
1.1. Moderate to vigorous physical activity (MVPA) from the accelerometer, operationalised as a walking cadence of >100 steps/minute (only collected at baseline, post-intervention, and the 12-month follow-up)1.2. Proportion of participants reaching the World Health Organization recommendation of at least 150 min/week of MVPA (only collected at baseline, post-intervention, and the 12-month follow-up)
1.3. International Physical Activity Questionnaire, short form (IPAQ-SF)
1.4. Steps/day (as operationalized in the primary outcome measure above) will also be collected at the 12-month follow-up, following the post-intervention (primary endpoint)
2. Food habits, measured using the 15-item Food Frequency Questionnaire (FFQ).
3. Risk consumption of alcohol, measured using the Alcohol Use Disorder Identification Test for Consumption (AUDIT-C).
4. Tobacco/nicotine use, evaluated by asking self-reported questions about current or previous use of cigarettes, snus or other tobacco or nicotine products. If current use, or if they quit during the last 6 months, participants are asked to specify frequency (daily, sometimes) and amount used.
5. Stress, measured with the Perceived Stress Scale (PSS).
6. Sleep pattern, measured with the Insomnia Severity Stress Index (ISI).

CARDIOMETABOLIC RISK:
Anthropometric and physiological measures (only collected at baseline, post-intervention, and the 12-month follow-up):

1. Waist circumference, measured in a standing position, midway between the lower rib margin and the iliac crest.
2. Sagittal abdominal diameter, measured in a supine position at the nearest 0.1 cm with a ruler and a water lever or a calliper, at the level of the umbilicus.
3. Weight, measured in kilograms, to the nearest 0.1 kg.
4. Body Mass Index (BMI), derived by dividing weight (in kilograms measured to the nearest 0.1 kg) by height (in meters measured to the nearest 0.1 cm) squared.
5. Systolic and diastolic blood pressure, measured in a seated position after ten minutes of rest, with a standard sphygmomanometer. The measurement will be taken twice, with 1 minute between measures. The means of the two systolic blood pressure and diastolic blood pressure measurements will be calculated to be used in the analyses.
6. Resting heart rate, measured in a seated position following a 5-minute rest.

Laboratory measures in blood (only collected at baseline, post-intervention, and the 12-month follow-up):
Blood will be drawn following an overnight fast (minimum 8 hours, or else rescheduled). The following parameters will be analysed:
1. Total cholesterol (mmol/l), S-low density lipoprotein cholesterol (mmol/l), S-high density lipoprotein cholesterol (mmol/l), and lipoprotein (a) (nmol/l).
2. Fasting triglycerides (mmol/l).
3. Fasting plasma glucose (mmol/l).
4. Glycated haemoglobin (HbA1c, mmol/l): This reflects average plasma glucose over the previous 8-12 weeks.
5. Blood status, including red and white cell count, thrombocyte count, and red blood cell measures/concentration.
6. Thyroid-stimulating hormone (TSH).
7. Vitamin, amino acid, and iron levels, including cobalamin/B12, homocysteine, 25-OH-D-vitamin, folate, and iron deposits (including iron [Fe] and transferrin).
8. High-sensitive C-reactive protein (hsCRP).
9. Inflammatory and genetic biomarkers, including white blood cell telomere length, inflammation panel, extracellular vesicles, and epigenetic age. These parameters will be analysed only at baseline and post-intervention.

CLINICAL MEASURES:
1. Obsessive-compulsive symptom severity will be measured with the clinician-administered Yale-Brown Obsessive Compulsive Scale (Y-BOCS) and the self-reported Obsessive-Compulsive Inventory – 12 (OCI-12).
2. Depressive symptoms, measured with the Patient Health Questionnaire (PHQ-9). The PHQ-9 will additionally be applied at mid-intervention (week 7).
3. Functional impairment, measured with the Work and Social Adjustment Scale (WSAS).
4. Health-related quality of life, measured with the EuroQol five-dimensional five-level questionnaire (EQ-5D-5L).

COST-EFFECTIVENESS:
The cost-effectiveness analysis will use two of the previously described outcomes:
1. The primary outcome, change in physical activity measured in steps/day.
2. The health-related quality of life measure (EQ-5D-5L), which will be used to estimate Quality Adjusted Life
Years (QALYs).

OTHER MEASURES:
1. Demographic data, including age, gender, educational level, occupational status, ongoing

psychological treatments, and current medication. Collected only at baseline.
2. Concurrent interventions, including questions on any treatment changes (e.g., changes in medication, initiation of psychological treatment) and/or initiation of concurrent interventions to improve lifestyle habits (including e.g., vitamin supplements) or cardiometabolic risk factors. This will additionally be collected at mid-intervention (week 7).
3. Adverse events, measured at mid-intervention (week 7) and post-intervention, using a short questionnaire created by the research team with items enquiring about increased anxiety, headaches, increased tiredness, musculoskeletal pain, etc. Participants will also be able to write their own examples on negative experiences connected to participation in the intervention.

Previous secondary outcomes:
All secondary outcome measures will be collected at post-intervention (primary endpoint) and 3, 6, and 12 months after the primary endpoint, unless otherwise specified.

LIFESTYLE HABITS:
1. Physical activity and activity level/sedentary behaviour will be evaluated using the following measures:
1.1. Moderate to vigorous physical activity (MVPA) from the accelerometer, operationalised as a walking cadence of >100 steps/minute
1.2. Proportion of participants reaching the World Health Organization recommendation of at least 150 min/week of MVPA
1.3. International Physical Activity Questionnaire, short form (IPAQ-SF). 4) Steps/day (as operationalized in the primary outcome measure above) will also be collected at all subsequent timepoints following the post-intervention (primary endpoint).
2. Food habits, measured using the 15-item Food Frequency Questionnaire (FFQ).
3. Risk consumption of alcohol, measured using the Alcohol Use Disorder Identification Test for Consumption (AUDIT-C).
4. Tobacco/nicotine use, evaluated by asking self-reported questions about current or previous use of cigarettes, snus or other tobacco or nicotine products. If current use, or if they quit during the last 6 months, participants are asked to specify frequency (daily, sometimes) and amount used.
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3. Weight, measured in kilograms, to the nearest 0.1 kg.
4. Body Mass Index (BMI), derived by dividing weight (in kilograms measured to the nearest 0.1 kg) by height (in meters measured to the nearest 0.1 cm) squared.
5. Systolic and diastolic blood pressure, measured in a seated position after ten minutes of rest, with a standard sphygmomanometer. The measurement will be taken twice with 1 minute between measures. The means of the two systolic blood pressure and diastolic blood pressure measurements will be calculated to be used in the analyses.
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7. Vitamin, aminoacid, and iron levels, including cobalamin/B12, homocysteine, 25-OH-D-vitamin, folate, and iron deposits (including iron [Fe] and transferrin).
8. High-sensitive C-reactive protein (CRP).
9. Inflammatory and genetic biomarkers, including white blood cell telomere length, inflammation panel, extracellular vesicles, and epigenetic age. These parameters will be analyzed only at baseline and post-intervention.

CLINICAL MEASURES:
1. Obsessive-compulsive symptom severity will be measured with the clinician-administered Yale-Brown Obsessive Compulsive Scale (Y-BOCS) and the self-reported Obsessive-Compulsive Inventory – 12 (OCI-12).
2. Depressive symptoms, measured with the Patient Health Questionnaire (PHQ-9). The PHQ-9 will additionally be applied at mid-intervention (week 7).
3. Functional impairment, measured with the Work and Social Adjustment Scale (WSAS).
4. Health-related quality of life, measured with the EuroQol five dimensional five level questionnaire (EQ-5D-5L).

COST-EFFECTIVENESS:
The cost-effectiveness analysis will use two of the previously described outcomes:
1. The primary outcome, change in physical activity measured in steps/day.
2. The health-related quality of life measure (EQ-5D-5L), which will be used to estimate Quality Adjusted Life Years (QALYs).

OTHER MEASURES:
1. Demographic data, including age, gender, educational level, occupational status, ongoing psychological treatments, and current medication. Collected only at baseline.
2. Concurrent interventions, including questions on any treatment changes (e.g., changes in medication, initiation of psychological treatment) and/or initiation of concurrent interventions to improve lifestyle habits (including e.g., vitamin supplements) or cardiometabolic risk factors. This will additionally we collected at mid-intervention (week 7).
3. Adverse events, measured at mid-intervention (week 7) and post-intervention, using a short questionnaire created by the research team with items enquiring about increased anxiety, headaches, increased tiredness, musculoskeletal pain, etc. Participants will also be able to write own examples on negative experiences connected to participation in the intervention.

Completion date
01/02/2028

Eligibility

Key inclusion criteria

1. Meeting criteria for OCD, based on the diagnostic criteria of the 5th edition of the Diagnostic and Statistical Manual of Mental Disorders.
2. Physical inactivity/sedentarism, operationalized as less than 150 minutes of physical activity per week during the last month, evaluated by asking two questions from the National Board of Health and Welfare concerning: a) frequency of weekly moderate or vigorous intensity physical exercise, and b) frequency of weekly non-exercise/daily life physical activity.
3. Aged 18 years or older.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Intellectual disability or severe psychiatric symptoms or suicidal risk that could interfere with the intervention
2. A diagnosis of an eating disorder or a substance use disorder
3. Being pregnant or <1 year postpartum
4. Myocardial infarction or stroke within the last 6 months
5. Cardiovascular risk measures significantly over the normal range (e.g., severe hypertension [blood pressure above ≥180 mmHg systolic or ≥110 mmHg diastolic]) or a current somatic condition that make participation in the intervention contraindicated
6. Initiation or adjustment of any cardiometabolic medication (e.g., blood pressure or blood lipids lowering mediation) within 3 months prior to assessments
7. Inability to understand and communicate in Swedish
8. Inability to consistently attend the sessions involved in the intervention
9. Inability to travel to the sessions involved in the intervention

Date of first enrolment
30/01/2026

Date of final enrolment
01/11/2027

Locations

Countries of recruitment
Sweden

Study participating centre
OCD-programmet, Psychiatry Southwest, Karolinska University Hospital [Karolinska Universitetssjukhuset]
Röntgenvägen 3, plan 13, Flemingsbergs centrum
Stockholm
Sweden
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Sponsor information

Organisation
Psychiatry Southwest [Psykiatri Sydväst], Stockholm Healthcare Services [Stockholms läns sjukvårdsområde (SLSO)], Region Stockholm

Funder(s)

Funder type
Charity

Funder Name
Hjärt-Lungfonden (Swedish Heart and Lung Foundation)

Alternative Name(s)
Swedish Heart-Lung Foundation, Hjart Lungfonden

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Funder Name

Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Forskningsrådet för hälsa, arbetsliv och välfärd

Alternative Name(s)
Swedish Research Council for Health, Working Life and Welfare, Forskningsrådet om Hälsa, Arbetsliv och Välfärd, FORTE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Region Stockholm

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Funder Name
Kricastiftelsen (Krica Foundation)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date