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The effects of bicycling exercise in people with lower limb lymphedema

Submission date	**Recruitment status**	[_] Prospectively registered
25/10/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/02/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/01/2025	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

Exercise is of main importance in cancer rehabilitation since it has been shown that higher levels of exercise can lower the risk of cancer recurrence and death. Lymphedema (tissue swelling) in the limbs is a well-known side-effect of cancer treatment (secondary lymphedema) but can also be congenital (primary lymphedema). Previously it was assumed that moderate and vigorous exercise may overload the lymphatic system, but nowadays it has been proven that progressive regular exercise is safe and does not worsen the lymphedema. Recently few studies suggested that lymphedema in the lower limb may even improve, in particular when the exercise frequency is high. These studies have some limitations however such as few participants, short duration of exercise or lack of a control group, and therefore more studies are needed. The aim of this study is to evaluate if high-frequency moderate-intensity bicycling exercise is feasible and effective for improving lymphedema status, physical fitness and quality of life in persons with lower limb lymphedema (LLL).

Who can participate?

Patients aged 18 years and over with chronic uni-or bilateral, primary or secondary LLL. The lymphedema should be persistent for at least 6 months with a volume variation of less than 5% for each limb during the last 6 months. No recurrence of the cancer or concurrent diseases or medication affecting the limb/limbs should be present.

What does the study involve?

The participants will be randomly allocated to either the exercise group (bicycling 3 to 5 times a week for 8 weeks), or to the control group (maintaining usual daily routines). For the exercise group the bicycling will be performed on their own using a private bike or an indoor bike provided by the research team. Each exercise session will last for 30 to 60 minutes. A heart rate monitor will be provided to maintain the moderate intensity and a logbook will be used to register each exercise session and any adverse event related to the exercise. Compression stockings will be used daily or day and night according to usual care. If the stockings are older than 2 months at start of the study new ones will be used for 2 weeks before inclusion in the study.

What are the possible benefits and risks of participating?
The benefit of participating is to gain more knowledge about personal lymphedema status. For the exercise group the benefits are possible improvements related to the effects of the exercise. The possible risks for the exercise group are muscle soreness and a small risk of worsening the lymphedema. However, due to regular follow-ups, any adverse event or even a deterioration of the lymphedema will be detected quickly and treated immediately.

Where is the study run from?
Skåne University Hospital (Sweden)

When is the study started and how long is it expected to run for?
February 2016 to December 2022

Who is funding the study?
The Swedish Cancer Foundation (Sweden)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
The Swedish Cancer Foundation 19 0166 Pj01H

Study information

Scientific Title

The feasibility and effects of high-frequency moderate-intensity bicycling exercise in people with lower limb lymphedema: a randomized controlled pilot trial

Study objectives
High-frequency moderate-intensity bicycling exercise is feasible and more effective than regular daily activity, for improving lymphedema status, physical fitness and quality of life in persons with lower limb lymphedema

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/03/2016, the Swedish Ethical Review Authority (Lund University, Sandgatan 1, Box 133, 22100 Lund, Sweden; +46 (0)10 4750800; registrator@etikprovning.se), ref: Dnr: 2016/136
An amendment to include additional lymphedema clinics in the region was approved in December 2020, ref: Dnr 2020-05960

Primary study design
Interventional

Study design
Single-center interventional single-blinded randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lower limb lymphedema

Interventions
A total of 30 persons with stable lower limb lymphedema, will be randomized to either an exercise group or a control group with an allocation ratio of 2:1. The random allocation sequence will be performed using a computer software program. The exercise group will perform high-frequency moderate bicycling on their own, on a private bicycle either indoors or outdoors, or on an indoor bike provided by the research team or at a gym (if the participant has access to a gym). The exercise should be performed 3 to 5 times a week for 8 weeks with a mean intensity of 40-59% of the Heart Rate Reserve (HRR). Each session should last 30 to 60 minutes, corresponding to a perceived exertion rate of 12-14 on the Borg´s Rating of Perceived Exertion (RPE) Scale. A Polar heart rate monitor will be provided by us and used during all exercise sessions to monitor the heart rate. Before each exercise session there will be some warming-up exercises consisting of bicycling at a self-chosen speed for 5 minutes. After each session there will be a cool-down period consisting of bicycling at a self-chosen pace and stretching. At baseline, the participants in the exercise group will receive written information and verbal instructions about the exercise sessions, the Polar heart rate monitor, Borg´s RPE scale, the warming up, cooling down and stretching. A logbook will be used to register; i) the date for each exercise session; ii) the subjective sensation of heaviness and tightness in the lower limbs rated on a Visual Analog Scale, prior to each exercise session and after; iii) the total time for the exercise session in minutes; iv) average heart rate during the exercise session; v) any adverse events related to the performance of the exercise. The logbook will be checked by CJ every 2 weeks during the intervention together with the assessments of LL volume.

The participants randomized to the control group will be encouraged to maintain their usual daily routines during the 8-week period. If they are involved in any form of physical activity or exercise, regular or more spontaneously they will be allowed to continue with such activities.

Intervention Type
Behavioural

Primary outcome(s)
1. Lower limb volume, measured as circumferential measurements every 4th cm along the limb at baseline and after 8 weeks. The formula of a truncated cone is used to calculate the total limb volume
2. Local tissue water, measured at 14 different points on the calf and thigh by the MoistureMeterD at baseline and after 8 weeks
3. Arm-to-leg impedance, calculated by measurements of the impedance to extracellular fluid by bioimpedance spectroscopy (BIS) at baseline and after 8 weeks

Key secondary outcome(s)
1. Cardiovascular fitness measured by a submaximal ergometer test at baseline and after 8 weeks
2. Health-related quality of life measured by the questionnaire Lymphedema Quality of Life Inventory (LyQLI) at baseline and after 8 weeks
3. Impairments, activity limitations and participation restrictions related to the lower limb lymphedema, measured by the questionnaire Lymph-ICF-LL at baseline and after 8 weeks
4. Perception of heaviness and tightness in the lymphedema limb/ limbs measured by the Visual Analogue Scale (VAS) at baseline and after 8 weeks
5. Leisure time physical activity during the last 6 months measured by the Saltin-Grimby Physical Activity Level Scale at baseline

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Uni-or bilateral, primary or secondary lower limb lymphedema
3. Persistent lymphedema for at least 6 months
4. A volume variation of less than 5% for each limb during the last 6 months

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Recurrence of cancer disease
2. Language limitations or dementia
3. Presence of concurrent diseases or medication affecting the limb volume or inability to perform bicycling exercise

Date of first enrolment
21/11/2018

Date of final enrolment
01/11/2022

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital
Department of Hematology, Oncology and Radiation Physics
Lymphedema Unit
Lasarettsgatan 23 A
Lund
Sweden
22185

Study participating centre
Centralsjukhuset Kristianstad
Fysioterapimottagning
J A Hedlunds väg 5
Kristianstad
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29133

Study participating centre
Lasarettet i Ystad
Rehabiliteringsmottagning
Thorssons väg 17
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Sponsor information

Organisation
Lund University

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
Charity

Funder Name
Swedish Cancer Foundation

Alternative Name(s)

Funding Body Type
Private sector organisation

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

Location
Sweden

Funder Name
Swedish Association of Chronic Oedema

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. Data will be saved anonymously at Skåne University Hospital in accordance with Swedish ethical rules. Study protocols and participant IDs are stored separately and locket in a file cabinet. Only researchers that are involved in the project will have access to the data.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			07/11/2022	No	Yes
Protocol file			07/11/2022	No	No