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Limb swelling under control - effective therapies and modern diagnostics

Submission date 31/05/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 03/06/2025	**Overall study status** Ongoing	
Last Edited 03/06/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Lymphedema is a chronic condition causing limb swelling due to fluid buildup. This study evaluates modern physiotherapeutic techniques to improve limb function and reduce symptoms. It aims to test diagnostic tools and therapies like compression, exercises, and kinesiotaping to enhance circulation and prevent relapses.

Who can participate?
Adults aged 18–80 years with a diagnosis of secondary lymphedema in one limb (stages I–III) are eligible. Participants must be in stable condition and able to follow instructions. Healthy volunteers without swelling history may be included in control groups.

What does the study involve?
Participants are randomly assigned to different treatment arms, such as resistance training, compression, kinesiotaping, or placebo. Interventions last 4 to 12 weeks, with 2–5 sessions weekly. Assessments are conducted before, immediately after, and up to 3 months after treatment. The study uses tools like ultrasound, myotonometry, and flowmetry to measure tissue condition and circulation.

What are the possible benefits and risks of participating?
Participants may benefit from improved limb function, reduced swelling, and better quality of life. Risks are minimal and may include mild discomfort during exercise or measurement. All procedures follow safety standards.

Where is the study run from?
1. Medical Centre Provita, Żory, Poland
2. Health Workshop, Wrocław, Poland
3. Feldbergklinik Dr. Asdonk GmbH, St. Blasien, Germany

When is the study starting and how long is it expected to run for?
March 2025 to November 2026

Who is funding the study?
Provita Medical Center (Poland)

Who is the main contact?
Dr Robert Trybulski, rtrybulski.provita@gmial.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
No. 1/01/2025

Study information

Scientific Title
Integrated approach to diagnostics and mechanical-hemodynamic therapy of changes in lymphedema – a physiotherapeutic perspective

Acronym
LIMF-HEMO-MECH

Study objectives
1. The Kuhnke method provides reliable and valid limb volume measurements in patients with lymphedema compared to gold-standard techniques such as water volumetry and bioimpedance.
2. The severity of lymphedema influences the hemodynamic response of the microcirculation, as

measured by post-occlusive reactive hyperemia (PORH), with reduced perfusion in more advanced stages.
3. The application of kinesiotaping in patients with upper limb lymphedema significantly enhances PORH parameters, indicating improved microvascular function.
4. Intermittent pneumatic compression (IPC) combined with resistance exercises improves muscle stiffness, tension, strength, and microcirculatory response in patients with chronic lymphedema more effectively than exercises alone.
5. A comprehensive educational program and self-management strategies reduce recurrence rates of lymphedema and improve quality of life over a 12-month observation period compared to standard care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/03/2025, Ethics Committee at the Polish Physiotherapy Association (ul. Zygmunta Modzelewskiego 37, Warsaw, 02-679, Poland; +48 (0)502591428; biuro@fizjoterapeuci.org), ref: no 1/03/2025

Study design
Multiphase mixed-method randomized controlled trial with parallel and crossover designs

Primary study design
Interventional

Study type(s)
Other, Quality of life, Treatment

Health condition(s) or problem(s) studied
Lymphedema

Interventions
This is a randomized controlled trial. Participants are randomly assigned (1:1) to intervention or control groups using a sequence generated via randomizer.org. The study includes several interventional arms:
(A) Strength training for cervical pain
(B) Strength training for lumbar pain
(C) Plyometric training for football players
(D) Occlusion training (BFR) with varying arterial occlusion pressures (60%, 80%, 100%)
(E–F) BFR combined with magnetotherapy or sham therapy in patients with type 2 diabetes

Control groups receive either sham interventions (e.g., placebo cuff pressure or no plyometric training) or standard physiotherapy. Interventions last 4–12 weeks, depending on the group, with session frequency ranging from 2 to 5 times per week.

Outcomes are assessed at baseline, immediately post-intervention, and at 1 week, 1 month, and 3 months post-intervention. The study evaluates biomechanical parameters (muscle tone, stiffness, elasticity), perfusion, pain thresholds, and strength outcomes using validated tools (e.g., Myoton, LDF, ForceDecks, algometer).

Intervention Type

Mixed

Primary outcome(s)
1. Muscle elasticity measured using shear wave elastography (Sonoscape P20, linear probe 5–20 MHz) at baseline, post-intervention, and at 1 week, 1 month, and 3 months
2. Limb volume assessed using:
2.1. Kuhnke method (manual circumference-based calculation) at baseline, post-intervention, and at 1 week, 1 month, and 3 months
2.2. Water volumetry (immersion tank, ±5 ml precision) at baseline, post-intervention, and at 1 week, 1 month, and 3 months
3. Muscle tone, stiffness, and elasticity measured by MyotonPRO (Hz, N/m, arbitrary units) at baseline, post-intervention, and at 1 week, 1 month, and 3 months
4. Isometric muscle strength measured with ForceDecks (kgf) at baseline and post-intervention.
5. Reactive strength index (RSI) measured with ForceDecks (m/s) at baseline and post-intervention.
6. Perfusion parameters measured using laser doppler flowmetry (PeriFlux 5000): resting flow, biological zero (BZ), time to biological zero (BZt), time to reperfusion (TR), maximal hyperemic peak (MHP) at baseline and follow-ups

Key secondary outcome(s))
1. Muscle thickness measured using ultrasound (Sonoscape P20) at baseline and post-intervention
2. Perceived fatigue level measured using Borg RPE scale (6–20) before and after sessions
3. Perfusion parameters measured using laser Doppler flowmetry (LDF): time to return to baseline (TR), BZ/RF ratio at baseline and follow-ups
4. Motor preparation and recovery habits measured using a custom questionnaire once at baseline

Completion date
30/11/2026

Eligibility

Key inclusion criteria
1. Age 18–80 years
2. Unilateral lymphedema of the upper or lower limb (stage I, II or III according to the clinical classification)
3. Diagnosis of secondary lymphedema (e.g. after oncological, surgical or post-traumatic treatment)
4. Stable clinical condition, without signs of acute inflammation at the site of the swelling
5. No contraindications to physiotherapy, compression therapy, pneumocompression or exercise testing
6. Ability to move independently and follow simple instructions of a physiotherapist
7. Consent to participate in the study expressed in writing after reading the informed consent form

In the case of control groups: no active lymphedema and no history of treatment related to the swelling

Participant type(s)
Healthy volunteer, Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
150

Key exclusion criteria
1. Diagnosed cardiovascular diseases, such as: heart failure, unstable hypertension (blood pressure >140/90 mmHg), thromboembolic disease
2. Active bacterial, viral or fungal infection in the limb affected by edema
3. Cancer during active treatment (chemotherapy, radiotherapy) or relapse of oncological disease
4. Edema of a non-lymphatic nature (e.g. varicose, renal, cardiogenic, lipid)
5. Open wounds, skin damage or inflammation in the areas of planned measurements or therapy application
6. Pregnancy or postpartum period
7. Neurological disorders affecting motor control (e.g. stroke, multiple sclerosis)
8. Psychiatric disorders that prevent informed consent and cooperation in the study
9. Use of painkillers or anti-inflammatory drugs less than 24 hours before measurement
10. Participation in another clinical trial in the last 30 days
11. Refusal to participate in the study or withdrawal of consent at any time

Date of first enrolment
15/07/2025

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
Germany

Poland

Study participating centre

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Study participating centre
Health Workshop
ul. Przyjazni 58/4u
Wrocłalaw
Poland
53-030

Study participating centre
Feldbergklinik Dr. Asdonk GmbH
Luisenstraße 18
St. Blasien
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D-79837

Sponsor information

Organisation
Provita Medical Centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Provita Medical Center

Results and Publications

Individual participant data (IPD) sharing plan

All data collected during the study will be securely stored in compliance with GDPR regulations and institutional data protection policies. Participant-identifying information will be anonymized and data will be encrypted and stored on password-protected devices and institutional servers.

Access to raw or processed data will be restricted to authorized members of the research team. Data may be made available upon reasonable request for scientific or audit purposes, provided that it does not compromise participant confidentiality.

The principal investigator responsible for data storage and sharing is Dr Małgorzata Smoter (m.h.smoter@gmail.com).

IPD sharing plan summary

Available on request, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			03/06/2025	No	Yes
Participant information sheet			03/06/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes