

# Limb swelling under control - effective therapies and modern diagnostics

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<b>Registration date</b> 03/06/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## 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@gmail.com

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Mrs Smoter Małgorzata

### ORCID ID

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### Contact details

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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,  $\pm 5$  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**

**Medical Centre Provita Poland**  
al.Zjednoczonej Europy, 37  
Żory  
Poland  
44-240

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

**Study participating centre**  
**Feldbergklinik Dr. Asdonk GmbH**  
Luisenstraße 18  
St. Blasien  
Germany  
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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Participant information sheet</a>			03/06/2025	No	Yes
<a href="#">Participant information sheet</a>			03/06/2025	No	Yes