

Study Protocol

Official Title:

Clinical Evaluation of Kinesio Taping Outcomes in Stage II Cellulite: A Pilot Randomised Controlled Trial

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Sponsor/Collaborator:

Klaipėda State University of Applied Sciences (Klaipėdos valstybinė kolegija)

Background

Cellulite is a common skin condition characterized by dimpling and uneven surface texture, primarily affecting women. It is associated with changes in the dermis and subcutaneous tissue, impaired microcirculation, and lymphatic congestion. Kinesio taping is a physiotherapy technique that may improve microcirculation and skin structure, but evidence for its effectiveness in cellulite is limited.

Objectives

The primary objective of this pilot randomised controlled trial is to evaluate the effects of kinesio taping on dermis density and low echogenic band (LEB) thickness in women with stage II cellulite. Secondary objectives include assessing changes in thigh circumference, body composition, cellulite stage, and skin moisture.

Study Design

This is a two-arm, parallel-assignment, open-label, randomised controlled trial.

Participants are allocated to either an experimental group (kinesio taping) or a control group (no intervention).

Participants

Eligible participants are women aged 18–45 years with stage II cellulite and normal body mass index (BMI). Exclusion criteria include pregnancy, edema, obesity, thrombosis, and skin infections.

Intervention

Experimental group participants receive kinesio taping once weekly for four consecutive weeks. Fan-shaped elastic tape is applied with 0–15% tension to the buttocks and thighs at standard anatomical points (gluteus maximus, posterior thigh, anterior thigh). Control group participants do not receive any intervention during the study period.

Outcome Measures

Primary Outcomes:

- Change in dermis density (measured by high-frequency ultrasound, DermaLab Combo 4).
- Change in low echogenic band (LEB) thickness (measured by ultrasound).

Secondary Outcomes:

- Change in thigh circumference (20 cm below the greater trochanter).
- Change in body composition (fat percentage, fat mass, fat-free mass, basal metabolic rate, total body water).
- Change in cellulite stage (Nürnberg-Müller Scale, Callegari Soft Plus).
- Change in skin moisture (Callegari Soft Plus device).

Sample Size

A total of 38 participants were enrolled, with randomisation into two groups (n=17 experimental, n=17 control). Sample size was determined using power analysis for an independent t-test, accounting for a 10% dropout rate.

Statistical Analysis

Data will be analysed using SPSS v25.0. Statistical tests include independent t-tests, paired t-tests, and effect size calculations (Cohen's d, Hedges' g). Significance is set at $p<0.05$.

Ethical Approval

The study was approved by the institutional ethics committee on 27 December 2024 (Nr. SSV6-114). All participants provided written informed consent.