ISRCTN13717352 https://doi.org/10.1186/ISRCTN13717352

Kalevala traditional manual therapy for chronic low back pain: comparing its benefits to physiotherapy and healthcoachingsupported care

Submission date
02/03/2026

Recruitment status
No longer recruiting

Registration date
02/03/2026

Overall study status
Ongoing

Last Edited
02/03/2026

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Chronic low back pain (CLBP) is a major global cause of disability, and its management requires a biopsychosocial approach. The World Health Organization (2023) guidelines emphasize non-surgical interventions such as physiotherapy, patient education, and psychological support. In Finland, Kalevala Traditional Manual Therapy is a traditional manual therapy, the effects of which on pain and functional ability have been reported in pilot studies. Health coaching supports behavior change and may improve treatment outcomes. The aim of this study is to evaluate the effectiveness of Kalevala Traditional Manual Therapy and its combination with health coaching in the treatment of chronic low back pain, compared to physiotherapy.

Who can participate?
Adults (aged 18 years and over) who have experienced low back pain for at least 12 weeks without significant recovery

What does the study involve?
The treatment period lasts 8 weeks, with follow-up conducted at 6 months. Participants will attend a total of six study visits, including:
1. Baseline assessments, conducted over two visits: the first visit lasts approximately 60 minutes and the second approximately 30 minutes
2. Post-treatment assessments, conducted over two visits, each lasting approximately 30 minutes
3. Follow-up assessments, conducted over two visits, each lasting approximately 30 minutes
The number and content of treatment sessions vary depending on group allocation:
1. Physiotherapy group: three guidance sessions (30–60 min)
2. Kalevala Traditional Manual Therapy group: three Kalevala bone setting treatments (90 min)
3. Kalevala Traditional Manual Therapy and Health coaching: 3 Kalevala Traditional Manual

Therapy (90 min) and six health coaching sessions (30 min, by phone)
In addition, participants included in the acute effects measurements will undergo assessments 30 minutes before and again 30 minutes after the first treatment session.

What are the possible benefits and risks of participating?
It is possible that you will not benefit directly from participating in this study. However, the knowledge gained may help determine whether Kalevala Traditional Manual Therapy, either alone or combined with health coaching, is an effective treatment for chronic low back pain compared to physiotherapy.
The results may contribute to the development of cost-effective and patient-centered care models, inform clinical guidelines, and improve participants' pain, functional ability, quality of life, and physical activity. In this study, potential risks are generally mild and transient. Kalevala Traditional Manual Therapy may cause temporary pain or slight swelling, but serious adverse effects are very rare. Physiotherapy exercises may cause temporary muscle soreness, as is typical after exercise. The measurements are painless and do not pose any risk. Answering psychological questionnaires may evoke emotions, but participation in these is voluntary.

Where is the study run from?
University of Eastern Finland (Finland)

When is the study starting and how long is it expected to run for?
March 2026 to December 2028

Who is funding the study?
The Ministry of Finance (Finland)

Who is the main contact?
Mika Venojärvi, mika.venojarvi@uef.fi

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Mika Venojärvi

ORCID ID
https://orcid.org/0000-0003-1327-9760

Contact details
University of Eastern Finland, Yliopistonrinne 8
Kuopio
Finland
70210
+358 (0)403552248
mika.venojarvi@uef.fi

Additional identifiers

Study information

Scientific Title
Kalevala traditional manual therapy as an independent therapy and integrated into health coaching compared with physiotherapybased care in the management of chronic low back pain: a randomized controlled trial

Acronym
Kalevala

Study objectives
The aim of the study is to evaluate whether Kalevala Traditional Manual Therapy (KTMT), either as a standalone intervention or combined with health coaching, is as effective or more effective than physiotherapeutic treatment in individuals with chronic low back pain. The study also examines the number of sick-leave days and the use of medications 6 months after the completion of the intervention. In addition, the acute effects of both physiotherapeutic treatment and KTMT are assessed.

Research questions:
1. Does Kalevala Traditional Manual Therapy reduce pain and improve functional capacity more effectively than physiotherapeutic treatment?
2. Does the combination of Kalevala Traditional Manual Therapy and health coaching produce a greater treatment response than Kalevala Traditional Manual Therapy alone or physiotherapeutic treatment?
3. Do the interventions influence physical activity, quality of life, mood, and sleep quality during the 8week treatment period and the 6month followup?
4. Is the treatment response associated with changes in fearavoidance behaviors and physical activity?
5. Does Kalevala Traditional Manual Therapy, either alone or combined with health coaching, reduce the number of sickleave days and the use of analgesic medications compared with physiotherapeutic treatment during the 6month followup?
6. Do the immediate effects of physiotherapeutic guidance and Kalevala Traditional Manual Therapy differ in terms of autonomic nervous system function, pain, tissue temperature distribution, muscle stiffness, lumbar spine mobility, mood, hydration status, stress level, and swelling when measured immediately before and after the first treatment session?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2026, The Regional Medical Research Ethics Committee of Eastern Finland Collaborative Area (Pohjois-Savon hyvinvointialue, Puijonlaaksontie 2, Kuopio, 70211, Finland; + 358 (0)44 717 2102; tutkimuseettinentoimikunta@pshyvinvointialue.fi), ref: 62/2026 (207/2025)

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic low back pain

Interventions
This study is a randomized, controlled, threearm intervention trial with an 8week treatment period and a 6month followup. Participants are randomized into three groups (n = 35 per group). Randomization will be performed using a computer-assisted block method to ensure balance (age, sex) after the first study visit.

1. Physiotherapy (FT)
The physiotherapy program consists of three supervised physiotherapy sessions delivered during study weeks 1 (45–60 minutes), 3 (30 minutes), and 6 (30 minutes). During the remaining weeks, participants continue the exercises at home according to the physiotherapist's instructions. The program includes therapeutic exercises such as mobility, motorcontrol, corestabilization, and strengthtraining exercises, which are individually selected to support lumbar spine function. In addition, the homeexercise program includes aerobic activity, such as walking, which is progressively increased over the course of the program. The physiotherapy intervention is progressive, meaning that the volume and difficulty of the exercises are gradually increased while taking into account functional capacity and safety.

2. Kalevala Traditional Manual Therapy (KTMT)
Participants receive three KTMT treatment sessions over the 8week period. The manual therapy applied in the study is a gentle, noninvasive softtissue approach designed to support the body's natural mobility and balance. The treatment proceeds from the lower body toward the upper body in the following sequence: feet and ankles, lower legs, knees, thighs and hips, sacral and back region, upper limbs, and the head and cervical spine.
The techniques consist of soft, slow, tissueresponsive manual strokes intended to facilitate normal tissue movement, fluid circulation, and functional balance. The treatment does not include manipulations or highforce techniques. Each session lasts approximately 90 minutes.

3. Kalevala Traditional Manual Therapy + Health Coaching (KTMT+HC)
Participants receive three KTMT sessions as described above, together with six healthcoaching sessions. The coaching is delivered by phone for approximately 30 minutes per week during study weeks 1, 2, 3, 5, 6, and 7. The content focuses on key themes relevant to lowbackpain management: understanding the biopsychosocial model of back pain, reducing fearavoidance behaviors, increasing physical activity and functional capacity, strengthening individualized painmanagement strategies, and supporting home exercises.

During the first treatment session, the acute effects of physiotherapy guidance (45–60 min) (n = 30) and Kalevala Traditional Manual Therapy (90 min) (n = 30) are assessed on autonomic nervous system function, pain, tissue temperature distribution, muscle stiffness, lumbar spine mobility, mood, fluid balance, stress level, and swelling, immediately before and after the treatment.

Intervention Type
Mixed

Primary outcome(s)
1. Pain intensity measured using the Visual Analogue Scale (VAS) at baseline, 8 weeks, 6month followup

2. Disability related to low back pain measured using the Oswestry Disability Index (ODI) at baseline, 8 weeks, 6month followup

Key secondary outcome(s)
1. Quality of life measured using the RAND 36 Health Survey at baseline, 8 weeks, 6 month follow up

2. Mood measured using the Positive and Negative Affect Schedule (PANAS) at baseline, 8 weeks, 6 month follow up

3. Fear avoidance behavior measured using the Fear Avoidance Beliefs Questionnaire (FABQ) at baseline, 8 weeks, 6 month follow up

4. Function measured using the Patient-Specific Functional Scale (PSFS) at baseline, 8 weeks, 6 month follow up

5. Sleep quality measured using the Pittsburgh Sleep Quality Index (PSQI) at baseline, 8 weeks, 6 month follow up

6. Physical activity measured using the Global Physical Activity Questionnaire (GPAQ) at baseline, 8 weeks, 6 month follow up

7. Flexibility measured using the Fingertip to Floor Test (FTF) at baseline, 8 weeks, 6 month follow up

8. Lumbar flexion mobility measured using the Modified Schober Test (MST): at baseline, 8 weeks, 6 month follow up

9. Postural stability measured using the Romberg Test at baseline, 8 weeks, 6 month follow up

10. Muscle mechanical properties: muscle stiffness, tone (frequency), and elasticity (decrement) measured using a Myoton device at baseline, 8 weeks, 6 month follow up

11. Depressive symptoms measured using the Beck Depression Inventory (BDI) at baseline, 8 weeks, 6 month follow up

12. Sickness absence measured using the total number registry verified sick leave days at 6 month follow up

13. Use of analgesic medications measured using registry verified logs documenting type, dose, and frequency of pain medication use at 6 month follow up

Completion date
31/12/2028

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Chronic low back pain (>12 weeks)
3. Start Back Screening Tool score >3
4. Ability to participate in the treatment and followup period

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Pregnancy
2. Cardiac pacemaker or metallic prosthesis
3. Rheumatic diseases
4. Severe structural deformity
5. Previous spinal surgery
6. Acute disc herniation or severe sciatica

Date of first enrolment
09/03/2026

Date of final enrolment
30/08/2026

Locations

Countries of recruitment
Finland

Sponsor information

Organisation
University of Eastern Finland

ROR
https://ror.org/00cyydd11

Organisation
Kalevala Folk Healing Foundation

Organisation
Advisory Board for Traditional Therapies

Funder(s)

Funder type

Funder Name
The Ministry of Finance of Finland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available