Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Thermobalancing therapy and Dr Allen’s Device for the treatment of patients with chronic low back pain due to lumbar disc herniation or non-specific low back pain

Protocol summary

Study aim

To determine the effectiveness of thermobalancing therapy and Dr Allen’s Device for the treatment of patients with chronic low back pain (CLBP) due to lumbar disc herniation or non-specific low back pain

Design

Two arm parallel design randomized controlled trial.

Settings and conduct

The study will be conducted at Physical Therapy clinic of Government College University Faisalabad. Potential participants visiting clinic who fulfil edibility criteria will be provided with participant information sheet and if agree to participate, informed consent will be obtained. After baseline assessment participants will be randomized.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Subjects with chronic low back pain, age ≥18 years ≤ 70 years. Subjects should be diagnosed with lumbar disc herniation or nonspecific low back pain. Exclusion criteria: patients with lumbar spinal stenosis, lumbar spondylolisthesis, lumbar scoliosis, or a history of lumbar spine surgery. Also, should be excluded people with severe comorbidities including cancer, heart failure and chronic infectious diseases.

Intervention groups

Participants in the treatment group will receive thermobalancing with Dr Allen’s Device for 3 months. Dr Allen’s Device consist of a soft belt, which contains thermoelement(s) from the special mixture of natural waxes, is used. Participants will be guided to wear the belt for maximum time throughout the daytime. Patients in the control group will be placed in watchful waiting list and will not receive any active treatment.

Main outcome variables

Pain (Numerical Pain Rating Scale), functional disability (Roland Morris Disability Questionnaire) and low back pain symptoms (The Japanese Orthopedic Association Back Pain Evaluation Questionnaire) will be assessed at baseline, after 1 and 3 months after the treatment.

General information

Reason for update

The trial is completed

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052833N2**
Registration date: **2023-04-09, 1402/01/20**
Registration timing: **prospective**

Last update: **2024-02-13, 1402/11/24**
Update count: **1**

Registration date

2023-04-09, 1402/01/20

Registrant information

Name

Aatik Arsh

Name of organization / entity

Khyber Medical University

Country

Pakistan

Phone

+92 937 576111

Email address

aatikarsh@kmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-10, 1402/01/21

Expected recruitment end date

2023-06-25, 1402/04/04

Actual recruitment start date

2023-04-10, 1402/01/21

Actual recruitment end date

2023-06-25, 1402/04/04

Trial completion date

2023-06-30, 1402/04/09

Scientific title

Thermobalancing therapy and Dr Allen’s Device for the treatment of patients with chronic low back pain due to lumbar disc herniation or non-specific low back pain

Public title

Thermobalancing therapy for low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Subjects, age greater than 18 years and less than 70 years with chronic low back pain Subjects with diagnosis of lumbar disc herniation or nonspecific low back pain

Exclusion criteria:

Subjects with lumbar spinal stenosis, lumbar spondylolisthesis, lumbar scoliosis, or a history of lumbar spine surgery Subjects with severe comorbidities including cancer, heart failure and chronic infectious diseases

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Actual sample size reached: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

After completion of baseline Case report form, the participants (individuals) will be randomized to either the treatment or control group. Through simple randomization methods, participants will be randomized based on 1:1 allocation ratio. The randomization will be performed online based on a computer-generated randomization sequence using Openepi (www.openepi.com). The random sequence obtained from Openepi software will be stored with the trial data manager. After recruitment of the participant, research assistant will inform trial data manager to generate a randomization link from the software for the participant. After generating randomization link by the trial data manager, a research assistant will open the randomization link which will show the assigned group for the participants. The participant will be allocated to either treatment group or control group accordingly. The allocation will not be concealed as trail data manager, research assistant and participant will be aware of the allocation.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Review Committee of the Government College University Faisalabad

Street address

Chenab chowk , jhang road opposite Mr Winggs Faisalabad, Faisalabad, Punjab,38000

City

Faisalabad

Postal code

38000

Approval date

2021-10-03, 1400/07/11

Ethics committee reference number

GCUF/ERC/111

Health conditions studied

1

Description of health condition studied

Chronic low back pain due to lumbar disc herniation or nonspecific low back pain

ICD-10 code

M54.56

ICD-10 code description

Low back pain, lumbar region

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 1, 3 months after intervention

Method of measurement

Numerical Pain Rating Scale

2

Description

Disability

Timepoint

Before intervention and 1, 3 months after intervention

Method of measurement

Roland Morris Disability Questionnaire

3

Description
Low back pain symptoms
Timepoint
Before intervention and 1, 3 months after intervention
Method of measurement
The Japanese Orthopedic Association Back Pain Evaluation Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the treatment group will receive thermobalancing with Dr Allen's Device for 3 months. Dr Allen's Device consist of a soft belt, which contains thermoelement(s) from the special mixture of natural waxes, is used. Participants will be guided to wear the belt for maximum time (for at least 8 hours a day) throughout the daytime. A physical therapist will guide the participants how to wear the belt and how to remove it. Participants will be guided to note the number of days, on which they are not wearing the belt due to any reason. Participants will use diary to report the use and non-use of the belt.
Category
Treatment - Devices

2

Description
Control group: Patients in the control group will be placed in watchful waiting list and will not receive any active treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Government College University Faisalabad
Full name of responsible person
Muhammad Akram
Street address
Chenab chowk , jhang road opposite Mr Winggs Faisalabad, Faisalabad, Punjab,38000
City
Faisalabad
Postal code
38000
Phone
+92 345 2888394
Email
makram_0451@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fine Treatment
Full name of responsible person
Simon Allen
Street address
Pounsley House Pounsley Road, Dunton Green, Sevenoaks
City
Sevenoaks
Postal code
TN13 2XP
Phone
+44 7958 878300
Email
Info@finetreatment.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fine Treatment
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Foreign
Category of foreign source of funding
Sponsor: country of origin
Country of origin
GB
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Government College University Faisalabad Pakistan
Full name of responsible person
Muhammad Akram
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Chenab chowk , jhang road opposite Mr Winggs Faisalabad, Faisalabad, Punjab,38000
City
Faisalabad
Province
Pubjab
Postal code
38000

Phone
+92 41 9200670
Email
makram_0451@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Government College University Faisalabad Pakistan
Full name of responsible person
Muhammad Akram
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Chenab chowk , jhang road opposite Mr Winggs Faisalabad, Faisalabad, Punjab,38000
City
Faisalabad
Province
Pubjab
Postal code
38000
Phone
+92 41 9200670
Email
makram_0451@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Government College University Faisalabad Pakistan
Full name of responsible person
Muhammad Akram
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Chenab chowk , jhang road opposite Mr Winggs Faisalabad, Faisalabad, Punjab,38000
City
Faisalabad
Province
Pubjab
Postal code
38000
Phone
+92 41 9200670
Email
makram_0451@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The findiings of the trial will be published in a research jounral and all the documents will be attached as supplementary files.
When the data will become available and for how long
The data will be available right after the publication.
To whom data/document is available
The data/ documents will be available only for academicians/ researchers and clinicians.
Under which criteria data/document could be used
The data/ documents can be used only for academic purposes.
From where data/document is obtainable
From research journal website where the article will be published.
What processes are involved for a request to access data/document
No specific processes will be involved as relevant documents/data will be available as supplementary files with published article.
Comments

Trial results

Please tick if results have been published
Yes
Summary result posting date
2024-02-13, 1402/11/24
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2023-12-18, 1402/09/27

Abstract of published paper

BACKGROUND Lumbar disc herniation and non-specific low back pain are common conditions that seriously affect patients' health-related quality of life (HRQoL). Although empirical evidence has demonstrated that novel Thermobalancing therapy and Dr Allen's Device can relieve chronic low back pain, there have been no randomised controlled trials for these indications. AIM To evaluate the efficacy of Dr Allen's Device in lumbar disc herniation (LDH) and non-specific low back pain (NSLBP). METHODS A randomised clinical trial was conducted investigating 55 patients with chronic low back pain due to LDH (n = 28) or NSLBP (n = 27), out of which 15 were randomly assigned to the control group and 40 were assigned to the treatment group. The intervention was treatment with Dr Allen's Device for 3 mo. Changes in HRQoL were assessed using the Numerical Pain Rating Scale and the Japanese Orthopedic Association Back Pain Questionnaire. RESULTS Thermobalancing therapy with Dr Allen's Device showed a significant reduction in pain in the treatment group ($P < 0.001$), with no recorded adverse effects. Both pain assessment scales showed a significant improvement in patients' perception of pain indicating improvement in HRQoL. CONCLUSION The out-of-hospital use of Thermobalancing therapy with Dr Allen's Device for Low Back Treatment relieves chronic low back pain significantly and without adverse effects, improves the level of activity and HRQoL among patients with LDH and NSLBP. This study demonstrates the importance of this safe first-line therapy that can be used for effective at-home management of chronic low back pain. Allen S, Rashid A, Adjani A, Akram M, Khan FS, Sherwani R, Khalil MT. Efficacy and safety of thermobalancing therapy with Dr Allen's Device for chronic low back pain: A randomised controlled trial. World J Orthop 2023; 14(12): 878-888 [PMID: 38173805 DOI: 10.5312/wjo.v14.i12.878]