

# 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  $\geq 18$  years  $\leq 70$  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](http://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 trial 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 Wings  
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

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Government College University Faisalabad Pakistan

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

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## 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 journal 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]