

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the Role of Kinesiotaping as an Adjunct to Medication, Physiotherapy, and Exercises in on Low Back Pain: Clinical Outcomes from a Randomized Controlled Trial

Protocol summary

Study aim

The primary objective of this study is to evaluate the clinical outcomes of adding Kinesio taping to standard treatment modalities (medication, physiotherapy, and exercises) in patients with LBP, specifically in terms of pain relief, functional improvement, and overall recovery.

Design

This RCT with a parallel-group design compares Kinesio taping + standard care vs. standard care alone in 100 patients with Low Back Pain. Randomization & Allocation Participants will be randomly assigned to either: Intervention: Kinesio taping + standard care Control: Standard care alone Allocation: Concealed randomization Follow-Up Assessments at 24 hours, 3 days, and 1 week post-intervention.

Settings and conduct

Conducted in Clinical Settings, patients randomly allocated, and patients are not blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Adults aged 20-60 years • Diagnosed with chronic low back pain (non-specific) • Both genders • No recent back surgery or significant spinal abnormalities Exclusion Criteria: • Patients with inflammatory diseases (e.g., rheumatoid arthritis, ankylosing spondylitis) • Pregnant women • Skin allergies, wounds, or infections in the back area • Neurological deficits (e.g., sciatica, herniated disc) • Obesity (BMI > 30)

Intervention groups

The intervention group will have Kinesiotaping applied to the lumbar region based on standard KT methods for LBP. The tape will be applied for 3 consecutive days, following which it will be reapplied at regular intervals for one week. Physiotherapy and exercises will be administered as part of the treatment protocol for both groups. Medications, including nonsteroidal anti-inflammatory drugs (NSAIDs), will be prescribed based

on individual needs.

Main outcome variables

NRS and ODI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250308064979N1**

Registration date: **2025-03-30, 1404/01/10**

Registration timing: **retrospective**

Last update: **2025-03-30, 1404/01/10**

Update count: **0**

Registration date

2025-03-30, 1404/01/10

Registrant information

Name

Somaiya Ishaq

Name of organization / entity

Combined Military Hospital Kohat, Khyber Pukhtunkhwa, Pakistan

Country

Pakistan

Phone

+92 332 1946197

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-01, 1403/08/11

Expected recruitment end date

2025-01-01, 1403/10/12

Actual recruitment start date

2024-11-01, 1403/08/11

Actual recruitment end date

2025-01-01, 1403/10/12

Trial completion date

2025-01-01, 1403/10/12

Scientific title

Evaluating the Role of Kinesiotaping as an Adjunct to Medication, Physiotherapy, and Exercises in on Low Back Pain: Clinical Outcomes from a Randomized Controlled Trial

Public title

Effectiveness of Kinesiotaping on Pain Management in Lower Back: A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults aged 20-60 years diagnosed with chronic low back pain (non-specific)No recent back surgery or significant spinal abnormalities both genders

Exclusion criteria:

Patients with inflammatory diseases (e.g., rheumatoid arthritis, ankylosing spondylitis)Pregnant women Skin allergies, wounds, or infections in the back area Neurological deficits (e.g., sciatica, herniated disc) Obesity (BMI > 30)

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

his study employs a randomized controlled trial (RCT) design using a sample randomization method. Participants will be randomly assigned to either the Kinesio taping + standard care group or the standard care only group. Method of Randomization Type: Simple randomization Unit of Randomization: Individual participants Stratification Participants will be stratified based on: Age range: 20-60 years Pain severity level: Moderate and severe Randomization Process Software Used: SPSS Random Sequence Generation: Computer-generated randomization Random Allocation Process: Allocation will be conducted using a random sequence to ensure unbiased group assignment. Outcome Measures Numerical Rating Scale (NRS) will be utilized to assess pain levels. OSWESTRY Disability Index (ODI)

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Other Design Features are:

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board, Combined Military Hospital Kohat, Pakistan

Street address

Kohat Cantt

City

Kohat

Postal code

26000

Approval date

2024-09-20, 1403/06/30

Ethics committee reference number

E-2005/A/3

Health conditions studied**1****Description of health condition studied**

Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes**1****Description**

Pain Reduction by applying Kinesio Taping on Lower Back

Timepoint

Baseline (Pre-Intervention) 24 hours, 3 days and 1 week post application of Kinesio Taping

Method of measurement

Pain reduction will be assessed using a Numeric Rating Scale (NRS) from 0 to 10 where 0 indicates no pain and 10 indicates the worst pain imaginableParticipants will report their pain levels at baseline, 24 hours, 3 days and 1week post-application of Kinesio tape

Secondary outcomes**1****Description**

Improvement in functional ability of individuals with lower back pain.

Timepoint

Baseline (Pre-Intervention) 24 hours, 3 days and 1 week post application of Kinesio Taping

Method of measurement

Functional improvement will be assessed using the Oswestry Disability Index (ODI) to measure functional disability due to everyday activities such as standing, walking and lifting. Assessments will be conducted at baseline 24 hours 8days, and 1 week post application

Intervention groups

1

Description

Intervention group: Description Intervention group: Participants will receive Kinesio Taping (K Tape) applied to the Lower Back The tape will be worn continuously for 24 hours and functional improvements will be assessed at baseline, 24 hours, 3 days. and 1week post-application using the Numeric Rating Scale (NRS) and ODI

Category

Rehabilitation

2

Description

Control group: Participants will receive standard care (without KinesioTaping). Pain and functional improvements will be assessed at baseline 24hours, 3 days. and 1-week post-application using the Numeric Rating Scale (NRS) and ODI

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Physical Medicine and Rehabilitation
CMH Kohat KPK, Pakistan

Full name of responsible person

Dr. Syed Tameem UI Hassan

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital Kohat

Full name of responsible person

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Grant name

Government Institute

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Combined Military Hospital Kohat

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Combined Military Hospital Kohat

Full name of responsible person

Dr. Syed Tameem ul Hassan

Position

Major

Latest degree

Specialist

Other areas of specialty/work

Physiotherapy

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Latest degree
Bachelor

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

This dataset includes deidentified Individual Patient Data (IPD) from a randomized controlled trial assessing the impact of kinesio Taping on pain management in lower back. This datasheet consists of Demographics (age, gender), and grade of baseline assessment (ODI and NRS Scores) follow up results at 24 hours, 3 days and 1 week.

When the data will become available and for how long

This dataset will be made available upon request after study completion and publications of findings.

To whom data/document is available

The deidentified data will be available to researchers, clinicians and academic institutions conducting studies related to low back pain management, or rehabilitation interventions. Access will be granted upon formal request and approval

Under which criteria data/document could be used

The data will be shared only for academic and research purposes Researchers must submit a formal request with ethical approval for data usage. The dataset must not be used for commercial purposes of patient re-identification.

From where data/document is obtainable

Dataset is obtainable through formal request through emails

What processes are involved for a request to access data/document

A formal request is needed by official email.

Comments