

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

"Assessment of enhanced impact of Kinesio taping on Pain management in Knee Osteoarthritis - A Randomized controlled trial with standard care approaches"

Protocol summary

Study aim

the study aims to evaluate the short-term effects of Kinesio taping on pain reduction and functional improvement using the Numerical Rating Scale (NRS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Design

Randomized controlled trial (RCT), parallel-group design, comparing the effects of Kinesio taping with standard care versus standard care alone in patients with knee OA. A total of 100 participants randomly assigned to either the intervention group (Kinesio taping + standard care) or the control group (standard care alone) using concealed allocation. The study will follow up participants at 24 hours, 3 days, and 1 week post-intervention to assess outcomes.

Settings and conduct

conducted in clinical setting, patients randomly allocated and patients are not blinded

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Aged 40 to 80 years 2. Chronic knee pain 3. Ability to provide informed consent 4. Intact skin over knee Exclusion Criteria: 1. Presence of skin allergies, open wounds, or infections at the application site. 2. Diagnosed with inflammatory joint diseases. 3. Patients with neurological disorders 4. Pregnant

Intervention groups

Intervention group will receive Kinesio taping (K-tape) application on the affected knee joint in addition to standard care. Tape strip (5 cm wide, length adjusted to knee size) placed medially from the tibial tuberosity to the rectus femoris muscle and another strip laterally. At middle portion 30-40% tension, at ends 0% tension. The tape will remain in place for 24 hours, unless discomfort or skin irritation occurs, in which case it will be removed.

Main outcome variables

NRS and western Ontario and McMaster Universities

Osteoarthritis Index(WOMAC)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250303064920N1**

Registration date: **2025-03-06, 1403/12/16**

Registration timing: **retrospective**

Last update: **2025-03-06, 1403/12/16**

Update count: **0**

Registration date

2025-03-06, 1403/12/16

Registrant information

Name

Nimra Naeem

Name of organization / entity

Combined Military Hospital Kohat, Pakistan

Country

Pakistan

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+92 321 5770860

Email address

nimranaeem2020@gmail.com

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

"Assessment of enhanced impact of Kinesio taping on Pain management in Knee Osteoarthritis - A Randomized controlled trial with standard care approaches"

Public title

"Effectiveness of Kinesio Taping on Pain Management in knee Osteoarthritis : A Randomized Controlled Trial"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40-80 years Clinically Diagnosed with knee osteoarthritis (Grade 2-4) Chronic knee pain(On NRS) Consent to participate BMI limit Intact skin on knees Functional Limitations

Exclusion criteria:

Severe knee deformities Inflammatory diseases Chronic skin conditions Neurological disorders Overweight Pregnancy Skin Allergies Trauma Acute pain Open wounds

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

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

This study employs a randomized controlled trial (RCT) design using a simple randomization method. Participants will be randomly assigned to either the Kinesio taping + standard care group or the standard care-only group. Method of randomization: Simple randomization Unit of randomization: Individual participants. Stratification: Participants will be stratified based on age ranging (40-80 years) and pain severity level (moderate and severe). Tools used: software (e.g., SPSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) post-application, and NRS for pain. Random sequence generation: Random Allocation process

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board Combined Military Hospital Kohat, Pakistan

Street address

Combined Military Hospital Kohat

City

Kohat

Postal code

26000

Approval date

2024-09-20, 1403/06/30

Ethics committee reference number

E-2005/A/1

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M19.0

ICD-10 code description

Primary osteoarthritis of other joints

Primary outcomes

1

Description

Pain reduction by application of kinesio taping on knee joint

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 imaginable. Participants will report their pain levels at baseline, 24 hours, 3 days, and 1 week post-application of Kinesio tape."

Secondary outcomes

1

Description

Improvement in functional ability of the knee in individuals with osteoarthritis

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 Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC score evaluates pain, stiffness, and physical function, with higher scores indicating worse symptoms. Assessments will be conducted at baseline, 24 hours, 3 days, and 1 week post-application."(Provides a more detailed explanation of the WOMAC index and how it will be used.)

Intervention groups

1

Description

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

Category

Rehabilitation

2

Description

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

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 Ul Hassan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Nimra Naeem

Position

Physiotherapy Intern

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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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 knee osteoarthritis. The data consists of: Patient demographics (age, gender) Grade of knee OA Baseline assessment (WOMAC and NRS scores) Follow-up results at 24 hours, 3 days and 1 week post-application periods On excel sheet

When the data will become available and for how long

The dataset will be made available upon request after the study's completion and publication of findings.

To whom data/document is available

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

Under which criteria data/document could be used

Under Which Criteria the 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 or patient re-identification. Proper citation of the original study is required in any resulting publication.

From where data/document is obtainable

The dataset is available from [Combined Military Hospital]. Interested researchers can request access via email or official institutional request. Contact Information:03368885877 Email: drtameem2@gmail.com Address: Combined Military Hospital

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

1. Submit a formal request via email or institutional portal, detailing the purpose of data usage. 2. Provide ethical approval from their respective institution if applicable. 3. Sign a data-sharing agreement ensuring compliance with ethical guidelines and non-commercial usage. 4. Approval process: The request will be reviewed within [Specify Time, e.g., 2-4 weeks], and if approved, access will be granted via secure data transfer.

Comments

For any clarifications or additional information regarding data access, please contact [Nimra Naeem] at nimranaeem2020@gmail.com