Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects Of Pilates Exercises As A Treatment Approach In Patients With Non-specific Low Back Pain

Protocol summary

Study aim
1. To evaluate the impact of Pilates exercises on pain on people who have non-specific low back pain 2. To evaluate the effect of Pilates exercises on lumbar ROM in individuals with non-specific low back pain

Design
Randomized clinical trial with blinded outcome assessment. 30 male and female participants were randomly allocated into control and experimental groups.

Settings and conduct
Study settings were OPDs of Madinah teaching hospital and Allied hospital Faisalabad. The trial was blinded by both the researcher and the participants as someone else has allocated the participants in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria was to have individuals with chronic low back pain aging between 30-50 years. Exclusion criteria was pregnancy, any spinal pathology.

Intervention groups
Intervention group received hotpack as the baseline treatment then the participants had performed a set of Pilates exercise program which included 8 different exercises that basically targeted the core and lower back muscles while incorporating both mind and body.

Main outcome variables
Numeric pain rating scale and Modified Schober test were the main outcome measures. NPRS was to assess the pain and Modified Schober Test was used to assess the lumbar range of motion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221006056105N1**
Registration date: **2022-10-11, 1401/07/19**
Registration timing: **retrospective**
Last update: **2022-10-11, 1401/07/19**
Update count: **0**

Registration date
2022-10-11, 1401/07/19

Registrant information
Name
Saman Salahuddin
Name of organization / entity
Madinah Teaching Hospital Faisalabad
Country
Pakistan
Phone
+92 337 7002916
Email address
hashmisaman88@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-15, 1400/12/24

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
2022-03-20, 1400/12/29

Actual recruitment end date
2022-05-26, 1401/03/05

Trial completion date
2022-05-26, 1401/03/05

Scientific title
Effects Of Pilates Exercises As A Treatment Approach In Patients With Non-specific Low Back Pain

Public title
Effects Of Pilates Exercises For Non-specific Low Back Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
LBP that has proceeded longer than 3 months Male and female participants aging between 30-50 years Participants having complain of 3 to 7 score on NPRS No leg symptoms in last week No recent surgery in past 6 months
Exclusion criteria:
Pregnancy (all trimesters) Any history of spinal fracture Participants having pain due to other pathology (diagnostic triage for LBP) Ankylosing Spondylitis Participants enrolled in regular exercise programs

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Actual sample size reached: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The method used for randomization was chit and draw method. In this method, chits are prepared and assigned some numbers then they are randomly drawn to allocate participants in either of the two groups. Randomization was used to avoid biasness.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants were blinded in the study so that they did not know in which they were sent into. Blinding was done in order to avoid placebo effect. The participants were unaware of the treatmenr protocol given in both groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Of The University Of Faisalabad

Street address
Sargodha Road, University Town, Faisalabad

City
Faisalabad

Postal code
38000

Approval date
2022-06-19, 1401/03/29

Ethics committee reference number
7007

Health conditions studied

1

Description of health condition studied
Non-specific Low Back Pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Numeric Pain Rating Scale

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
It is a subjective 10 point pain assessment scale that a person describes according to his/her pain intensity.

Secondary outcomes

1

Description
Modified Schober Test

Timepoint
Before intervention and 4 weeks after intervention

Method of measurement
It is a test used to measure lumbar flexion and extension. A line was drawn 5 cm below and 10cm above the level of posterior superior iliac spine and the patients were instructed to forward flex and touch the toes, the measurements were taken using a measuring tape.

Intervention groups

1

Description
The participants of experimental/interventional group received hot pack as baseline treatment then performed Pilates exercises as treatment adjunct for 4 weeks of duration, 2 sessions per week. Measurements of pain intensity, lumbar range of motion were recorded at first and last session with measuring tools. The Pilates exercises program included Diaphragmatic breathing (as a warm up, slowly inhale and exhale as much as the patient could perform), The hundred (4 reps, 30 secs each), Roll up (5 reps, 30 secs), Spine stretch (5 reps with 2 minutes of recovery period within each rep), Single leg circles (5 reps each leg), Single leg circles with

bent leg (5 reps for each leg), Single leg stretch (5 reps for each leg) and Diaphragmatic breathing (to cool down the patient).

Category
Rehabilitation

2

Description
The participants of control group recieved hotpack as the baseline treatment and then they were instructed to continue their activities of daily living for 4 weeks, 2 sessions per week.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Madinah Teaching Hospital

Full name of responsible person
Saman Salahuddin

Street address
P 175, Shadman Town, Sargodha Road, Faisalabad

City
Faisalabad

Postal code
38000

Phone
+92 337 7002916

Email
hashmisaman88@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University Of Faisalabad

Full name of responsible person
Saman Salahuddin

Street address
P 175, Shadman Town, Sargodha Road Faisalabad

City
Faisalabad

Postal code
38000

Phone
+92 337 7002916

Email
hashmisaman88@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
The University Of Faisalabad

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Madinah Teaching Hospital

Full name of responsible person
Saman Salahuddin

Position
Physiotherapist

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
P 175, Shadman Town, Sargodha Road, Faisalabad

City
Faisalabad

Province
Punjab

Postal code
38000

Phone
+92 337 7002916

Email
hashmisaman88@gmai.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Madinah Teaching Hospital Faisalabad

Full name of responsible person
Saman Salahuddin

Position
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Street address
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City
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Phone
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Fax

Email

hashmisaman88@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Madinah Teaching Hospital Faisalabad

Full name of responsible person

Saman Salahuddin

Position

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Street address

P 175 Shadman Town Sargodha Road Faisalabad

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available