Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of massage therapy, Dynamic Neuromuscular Stabilization exercises, and their combination on pain intensity, functional disability, and quality of life in men aged 45 to 65 years with chronic non-specific low back pain

Protocol summary

Study aim

Compare the effects of six weeks of massage, Dynamic Neuromuscular Stabilization exercises, and their combination on pain, disability, and quality of life in men with chronic non-specific low back pain.

Design

A randomized, three-arm parallel group clinical trial on 60 patients. A computer-generated simple random sequence will be used for allocation. This study is not blinded for participants but includes blinded outcome assessment and blinded data analysis.

Settings and conduct

The study will be conducted at rehabilitation centers affiliated with the University of Sistan and Baluchestan. After obtaining informed consent and baseline assessments, patients will be randomly allocated into three groups. After 6 weeks of intervention, post-test evaluations will be performed. Due to the physical nature of the interventions, participants and therapists cannot be blinded. However, the outcome assessor evaluating the questionnaires and the statistical data analyst will be strictly blinded to the group allocations.

Participants/Inclusion and exclusion criteria

Inclusion: Men aged 45 to 65 years; chronic non-specific low back pain for at least 3 months; no similar exercises in the past 6 months. Exclusion: Specific causes of back pain (e.g., disc herniation, fractures); severe spinal or limb injuries; medications affecting pain or function; interfering diseases.

Intervention groups

Group 1: Dynamic Neuromuscular Stabilization exercises (3 sessions/week, 45 minutes) for 6 weeks. Group 2: Swedish massage (3 sessions/week, 30 minutes) for 6 weeks. Group 3: Combined exercises and massage for 6 weeks.

Main outcome variables

Pain intensity; Functional disability; Quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211201053244N7**
Registration date: **2026-05-02, 1405/02/12**
Registration timing: **prospective**

Last update: **2026-05-02, 1405/02/12**
Update count: **0**

Registration date

2026-05-02, 1405/02/12

Registrant information

Name

Mohammadreza Rezaeipour

Name of organization / entity

University of Sistan and Baluchestan

Country

Iran (Islamic Republic of)

Phone

+98 54 3113 2241

Email address

rezaeipour@ped.usb.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-10, 1405/02/20

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of massage therapy, Dynamic Neuromuscular Stabilization exercises, and their combination on pain intensity, functional disability, and quality of life in men aged 45 to 65 years with chronic non-specific low back pain

Public title

Effect of massage therapy and Dynamic Neuromuscular Stabilization exercises on pain, disability, and quality of life in men with chronic low back pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men aged 45 to 65 years. Diagnosis of chronic non-specific low back pain lasting at least 3 months. No participation in similar exercise programs during the previous 6 months. Ability to attend intervention sessions and complete study assessments. Provision of written informed consent.

Exclusion criteria:

Specific causes of low back pain, including disc herniation, spinal stenosis, or vertebral fracture. Severe injury of the spine, hip, knee, or ankle. Presence of other diseases that interfere with safe participation or study outcomes. Use of medications that significantly affect pain or physical function.

Age

From **45 years** old to **65 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After baseline assessment and confirmation of eligibility, participants will be randomly allocated in a 1:1:1 ratio to three parallel groups: Dynamic Neuromuscular Stabilization exercise, massage therapy, and combined Dynamic Neuromuscular Stabilization plus massage therapy. The unit of randomization is the individual participant. A computer-generated simple random sequence will be used. The allocation sequence will be prepared by a researcher not involved in recruitment or outcome assessment, and assignments will be placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. No stratification will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the physical interventions (Dynamic Neuromuscular Stabilization exercises and massage therapy), blinding of the participants and care providers (therapists/instructors) is not possible. However, to minimize detection and performance bias, the outcome assessor responsible for administering the questionnaires (VAS, Oswestry Disability Index, and SF-36) will be strictly blinded to the participants' group allocations. Furthermore, the data analyst will be blinded by receiving a coded dataset (e.g., Groups A, B, and C) without revealing the actual intervention assigned to each code.

Placebo

Not used

Assignment

Parallel

Other design features

Three-arm, parallel-group, randomized clinical trial with pretest-posttest assessment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sistan and Baluchestan University

Street address

University Street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816745785

Approval date

2025-11-05, 1404/08/14

Ethics committee reference number

IR.USB.REC.1404.032

Health conditions studied

1

Description of health condition studied

Chronic nonspecific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description
Pain intensity score
Timepoint
Baseline (before the start of the intervention) and exactly 6 weeks after the start of the intervention.
Method of measurement
Visual Analogue Scale.

2

Description
Functional disability score
Timepoint
Baseline (before the start of the intervention) and exactly 6 weeks after the start of the intervention.
Method of measurement
Oswestry Disability Index questionnaire.

3

Description
Quality of life score
Timepoint
Baseline (before the start of the intervention) and exactly 6 weeks after the start of the intervention.
Method of measurement
36-Item Short Form Health Survey questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Twenty participants will receive Dynamic Neuromuscular Stabilization exercises for 6 weeks, 3 sessions per week, 45 minutes per session. Each session will include 10 minutes of warm up, 25 minutes of Dynamic Neuromuscular Stabilization exercises, and 10 minutes of cool down. The exercise intensity will be progressively adjusted according to participants' tolerance and feedback. The program will include diaphragmatic breathing, baby rock, bridge, bear crawl, side lying hip abduction, dead bug, and single leg bridge exercises.
Category
Rehabilitation

2

Description
Intervention group 2: Twenty participants will receive Swedish massage therapy for 6 weeks, 3 sessions per week, 30 minutes per session, administered by a trained massage therapist. The massage protocol will include effleurage, petrissage, and friction techniques applied to the lumbar and surrounding muscles. The duration of each session will be approximately 5 minutes of effleurage, 15 minutes of petrissage, and 10 minutes of friction.
Category
Rehabilitation

3

Description
Intervention group 3: Twenty participants will receive a combined intervention for 6 weeks, 3 sessions per week. Each session will include 45 minutes of Dynamic Neuromuscular Stabilization exercises and 30 minutes of Swedish massage therapy. The exercise component will consist of warm up, Dynamic Neuromuscular Stabilization exercises, and cool down. The massage component will include effleurage, petrissage, and friction techniques administered by a trained massage therapist.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Sistan and Baluchestan University
Full name of responsible person
Mohammadreza Rezaeipour.
Street address
Faculty of Education and Psychology, University of Sistan and Baluchestan, Daneshgah Blvd., Zahedan, Sistan and Baluchestan Province, Iran.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745639
Phone
+98 915 341 4047
Email
rezaeipour@ped.usb.ac.ir
Web page address
https://www.usb.ac.i

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Sistan and Baluchistan
Full name of responsible person
Dr. Nour Mohammad Yaghoubi
Street address
University Street
City
Zahedan
Province
Sistan-va-Balouchestan

Postal code
98167-45845
Phone
+98 54 3113 6245
Email
yaghoubi@mgmt.usb.ac.ir
Web page address
https://www.usb.ac.i

Grant name

Grant code / Reference number

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

Title of funding source
University of Sistan and Baluchistan

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
UN agencies and international organizations

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Mohammadreza Rezaeipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports Injuies and Corrective Movements
Street address
Faculty of Education and Psychology, University of Sistan and Baluchestan, Daneshgah Blvd., Zahedan, Sistan and Baluchestan Province, Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745639
Phone
+98 54 3113 2674
Email
rezaeipour@ped.usb.ac.ir
Web page address
https://www.usb.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Mohammadreza Rezaeipour
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Sports Injuries and Corrective Movements
Street address
Faculty of Education and Psychology, University of Sistan and Baluchestan, Daneshgah Blvd., Zahedan, Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745639
Phone
+98 54 3113 2674
Email
rezaeipour@ped.usb.ac.ir
Web page address
https://www.usb.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
University of Sistan and Baluchestan
Full name of responsible person
Mohammadamin Keyvanshokouh
Position
Master of Science Student
Latest degree
Master
Other areas of specialty/work
Sports Injury and Corrective Exercise
Street address
No. 54, Modares 69 St., Zahedan, Sistan and Baluchestan Province, Iran
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816745639
Phone
+98 54 3113 2674
Email
amin.keyvanshokuh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The data collected is part of a Master's thesis and belongs to the University of Sistan and Baluchestan. Sharing raw participant data is not currently covered by the institutional ethical approval or participant consent

forms. There is no further information.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Study protocol registered in the Iranian Registry of Clinical Trials; statistical analysis plan described in the approved thesis proposal and final thesis; final clinical study report in the form of the approved Master's thesis and any published article derived from the study. No individual participant data, informed consent forms, or analytic code will be shared.

When the data will become available and for how long

The study protocol will be available after trial registration. The statistical analysis plan and final clinical study report will be available after thesis approval and completion of the study. These documents will remain available for 5 years after thesis approval or publication of the main results, whichever occurs later.

To whom data/document is available

These documents will be available to researchers affiliated with academic or research institutions.

Under which criteria data/document could be used

Access will be granted for academic and non commercial scientific use only. Applicants must submit a written request describing the research purpose and intended use of the documents. Use of the documents requires proper citation of the original study and approval by the principal investigator and supervisor.

From where data/document is obtainable

The study protocol will be obtainable from the Iranian Registry of Clinical Trials public record. The statistical analysis plan and final clinical study report may be requested by email from the study team. Contact persons: Mohammadamin Keyvanshokouh, amin.keyvanshokuh@gmail.com; Mohammadreza Rezaeipour, rezaeipour@ped.usb.ac.ir.

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

Applicants should send a written email request including their affiliation, research objective, and intended use of the requested documents. Requests will be reviewed by the study team within 2 to 4 weeks. If approved, the documents will be sent electronically in portable document format.

Comments

No further information.