Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of adding pain neuroscience education to high-load strengthening exercises on clinical and functional outcomes of participants with hyper mobility spectrum disorder

Protocol summary

Study aim

The general aim of the research is to compare the equivalence of adding pain neuroscience education to high-load strengthening exercises on clinical and functional outcomes of participants with hyper mobility spectrum disorder.

Design

The sample size is divided using G-POWER software - randomization method by choosing numbers from 1 to 45 (prepared by the trainer in advance and placed in sealed envelopes in the box) - research The present semi-experimental study was conducted in three groups - one blind strain - with a pre-test-post-test research design with two intervention groups and one control group.

Settings and conduct

It is done as a blind strain (outcome Assessor) in a sports club for 16 weeks.

Participants/Inclusion and exclusion criteria

The conditions for entering the study include the following: Women aged 18 - 65 with hyper mobility musculoskeletal pain in minimum one shoulder for at least three months and/or recurrent joint dislocations or joint instability without a reported history of trauma The following people are not eligible: Clinically suspected referred pain from the cervical spine Systemic inflammatory rheumatic diseases Connective tissue diseases e.g. Marfans, Stickler's or Loeys Dietz syndromes, Ehlers-Danlos Syndromes except hypermobile type Neurological diseases Pregnancy Steroid injection in the affected shoulder within three months

Intervention groups

Group 1: high-load strengthening exercises, group 2: combination of pain neuroscience education interventions and high-load strengthening exercises, group 3: control group (ergonomic recommendations and anatomy/physiology training).

Main outcome variables

Independent variable: pain neuroscience education and high-load strengthening exercises. Dependent variable: pain, self-report of joint laxity and instability, strength, shoulder range of motion, fear of movement.

General information

Reason for update

This update is performed to correct several inaccuracies in the original registration and to align the trial record with the final protocol and completed study. The main corrections include: (1) changing the gender of participants from “Both” to “Female” because only women were enrolled; (2) updating the inclusion and exclusion criteria to accurately reflect the final eligibility criteria used in the study; (3) correcting the randomization description, blinding status, and allocation concealment details; (4) changing the study design assignment from Factorial to Parallel; (5) updating the sample size (target and actual) to 45 participants; (6) correcting the ethics committee information; and (7) revising the primary and secondary outcome descriptions, intervention details, and other design features to match the actual conducted trial and the published manuscript.

Acronym

Pain Neuroscience Education (PNE) ,Hyper mobility spectrum disorder (HSD)

IRCT registration information

IRCT registration number: **IRCT20231118060102N1**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **prospective**

Last update: **2026-10-31, 1405/08/09**
Update count: **1**

Registration date

2024-09-26, 1403/07/05

Registrant information

Name

Pardis Garouee

Name of organization / entity

The University of Kharazmi

Country

Iran (Islamic Republic of)

Phone

+98 71 3632 7162

Email address

pardisgarouee@khu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-09, 1403/08/19

Expected recruitment end date

2025-01-19, 1403/10/30

Actual recruitment start date

2024-11-09, 1403/08/19

Actual recruitment end date

2025-01-19, 1403/10/30

Trial completion date

2025-02-15, 1403/11/27

Scientific title

Comparison of the effect of adding pain neuroscience education to high-load strengthening exercises on clinical and functional outcomes of participants with hyper mobility spectrum disorder

Public title

"Effect of adding pain neuroscience education to high-load strengthening exercises on clinical and functional outcomes of participants with hyper mobility spectrum disorder"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18–65 years Generalized joint hypermobility (GJH) defined by Beighton score:– ≥ 5 for women aged ≤ 50 years– ≥ 4 for women aged > 50 years– or one point below the age-specific cutoff when the five-part questionnaire (5PQ) is positive (at least two positive items) Presence of one or more of the following secondary symptomatic musculoskeletal manifestations:– Musculoskeletal pain in at least one shoulder for a minimum of three months– and/or recurrent atraumatic joint dislocation or joint instability involving at least two joints (including at least one shoulder), defined as any of the following:• At least three atraumatic dislocations of the same shoulder• At least two atraumatic dislocations in two different joints (including at least one shoulder) occurring at separate times• Medically confirmed joint instability in at least two joints (including at least one shoulder) not related to trauma

Exclusion criteria:

Clinically suspected referred pain from the cervical spine Systemic inflammatory rheumatic disease Heritable connective tissue disorders (e.g., Marfan, Stickler, or Loeys–Dietz syndromes) Neurological disorders Pregnancy, childbirth within the previous 12 months, or plans to become pregnant during the study Corticosteroid injection into the affected shoulder within the previous 3 months Shoulder surgery within the previous 12 months Inability to communicate verbally Inability or unwillingness to comply with the study protocol or provide informed consent

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible participants were randomly allocated in a 1:1:1 ratio to one of three groups using numbers from 1 to 45 prepared in advance by the treating instructor and placed in sealed opaque envelopes in a box. The randomization sequence remained concealed until completion of each participant’s baseline assessment, at which point the corresponding envelope was opened. A project manager not involved in outcome assessment or treatment delivery oversaw allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

This was a single-blind (assessor-blinded) trial. The outcome assessor who performed all baseline and post-intervention assessments remained blinded to group allocation throughout the study. Participants and the treating instructor could not be blinded due to the nature of the interventions (exercise and education). Participants were instructed not to disclose their group assignment during follow-up testing.

Placebo

Not used

Assignment

Parallel

Other design features

This was a single-blind (assessor-blinded), three-arm, parallel-group randomized controlled trial with a pre-test–post-test design. An a priori sample size calculation was performed using G*Power software for a repeated-measures ANOVA (group-by-time interaction as the effect of interest), assuming a medium effect size (Cohen’s f = 0.25), α = 0.05, 80% power, three groups and two measurement occasions. The required sample size was estimated at 42 participants; 45 participants (15 per group) were enrolled.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Research Institute of Physical Education and Sport Sciences

Street address
3, 5th Alley, Mirem ad Street, Motahari Street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1587958711

Approval date
2023-09-20, 1402/06/29

Ethics committee reference number
IR.SSRC.REC.1402.146

Health conditions studied

1

Description of health condition studied
Hypermobility spectrum disorder (HSD) with chronic shoulder symptoms / Shoulder hypermobility spectrum disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Shoulder-specific symptoms and functional disability

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Western Ontario Shoulder Instability Index questionnaire (21 items, total score ranging from 0 to 2100)

Secondary outcomes

1

Description
Shoulder pain intensity

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Numerical Pain Rating Scale (score range 0 to 10)

2

Description
Shoulder internal rotation muscle strength

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Hand-held dynamometer (force measured in kilograms)

3

Description
Shoulder external rotation muscle strength

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Hand-held dynamometer (force measured in kilograms)

4

Description
Shoulder internal rotation range of motion

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Universal goniometer (measured in degrees)

5

Description
Shoulder external rotation range of motion

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Universal goniometer (measured in degrees)

6

Description
Fear of movement

Timepoint
Baseline (before intervention) and immediately after the 16-week intervention

Method of measurement
Tampa Scale of Kinesiophobia-11 questionnaire

Intervention groups

1

Description
Intervention group: high-threshold strengthening exercises with pain neuroscience training. Three familiarization sessions (two weeks) with training approaches to deal with pain and how to implement exercises will be held in approximately three months. The first session is a group session for a duration of 30 minutes to an hour with a maximum of six participants in each group using a PowerPoint. The second session,

which includes three explanatory videos (online). The third session includes a 30-minute one-on-one conversation that relates the personal needs of the participants and the content to the pain neuroscience education. The contents of this group are about the physiology of pain and the nerve endings of pain.

Category

Rehabilitation

2

Description

Control group: Control group: The subjects of this group receive information on anatomy, physiology, the importance of self-care and ergonomic recommendations of Pasture.

Category

Other

3

Description

Intervention group: High-threshold strength training: weight training for 16 weeks, training twice a week (individually supervised) in a fitness center, consisting of 60 minutes of training for the first session, 30 minutes for subsequent sessions, and once a week (unsupervised) is done in one's own home. Their training program includes five exercises for shoulder muscles. The exercise intensity model is progressive with decreasing patterns between increasing periods.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rayka GYM

Full name of responsible person

Pardis Garouee

Street address

Pasdaran Street - the beginning of 72 Alley

City

Shiraz

Province

Fars

Postal code

7185994343

Phone

+98 938 413 4786

Email

pgarouee@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

kharazmi University

Full name of responsible person

Pardis Garouee

Street address

Iman Junubi Street - 19 Alley - No. 158

City

Shiraz

Province

Fars

Postal code

7185994343

Phone

+98 938 413 4786

Email

pgarouee@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

No external funding (Kharazmi University provided academic facilities)

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

kharazmi University

Full name of responsible person

Pardis Garouee

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Corrective Exercises

Street address

Iman Junubi St, 19 Alley, No. 158

City

Shiraz

Province

Fars

Postal code

7185994343

Phone

+98 938 413 4786

Email

pgarouee@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kharazmi University

Full name of responsible person
Pardis Garouee

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Corrective movements and pathology

Street address
Iman Junubi St,19 Alley, No. 158

City
Shiraz

Province
Fars

Postal code
7185994343

Phone
+98 71 3632 7162

Email
pgarouee@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kharazmi University

Full name of responsible person
Pardis Garouee

Position
Master of Science

Latest degree
Bachelor

Other areas of specialty/work
Corrective movements and pathology

Street address
South Iman Street, No. 158, 19 Alley

City
Shiraz

Province
Fars

Postal code
7185994343

Phone
+98 71 3632 7162

Email
pgarouee@gmail.com

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