Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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: Men and 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

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: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date

2024-09-26, 1403/07/05

Registrant information

Name

Pardis Garouee

Name of organization / entity

The University of Kharazmi

Country

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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
empty
Actual recruitment end date
empty
Trial completion date
empty

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:
Men and women aged 18 - 65 Generalized HSD (G-HSD) defined with Beighton score cut-off ≥ 5 for women up to the age of 50 years and ≥ 4 for those above 50 years and all men, if the Beighton score was 1 point below the age and sex-specific cut-off AND the five-part questionnaire (5PQ) was positive (= at least two positive items). Present with one or more secondary symptomatic musculoskeletal manifestations, defined as either 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 defined as either a) minimum three atraumatic dislocations in same shoulder, b) minimum two atraumatic dislocations in two different joints (minimum one in the shoulder) occurring at different times, or c) medical confirmation of joint instability in minimum two joints (minimum one in the shoulder) not related to trauma.
Exclusion criteria:
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 or childbirth within the past year or planning to get pregnant during the study period Shoulder surgery within the past year Steroid injection in the affected shoulder within three months Inability to speak Unable to comply with protocol
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
- Outcome assessor

Sample size
Target sample size: **47**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomly selecting participants involves choosing numbers from 1 to 45, which are prepared in advance by the instructor and placed in sealed envelopes in a box. The randomization sequence remains concealed until the completion of the baseline assessments of the patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
The evaluator (Outcome Assessor) is blinded to the allocation of groups so that the results are unbiased and accurate.The three groups in the study are supervised by a corrective movement instructor.
Placebo
Not used
Assignment
Factorial
Other design features
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.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Iran Sports Science Research Institute
Street address
Iman Junubi Street - 19 Alley - No. 158
City
Shiraz
Province
Fars
Postal code
7185994343
Approval date
2023-09-28, 1402/07/06
Ethics committee reference number
SSRI.REC-2307-2346

Health conditions studied

1

Description of health condition studied
Shoulder hypermobility disorder
ICD-10 code
Other diso
ICD-10 code description
XIII Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Adding pain neuroscience education to high-load strengthening exercises - clinical and functional variables (pain, strength, range of motion, fear of movement, shoulder function) in shoulder hyper mobility spectrum disorder
Timepoint
It is measured before the start and after 16 weeks.
Method of measurement
Western Ontario Questionnaire to assess the individual's self-report of joint laxity and instability - Hand-held dynamometer to measure muscle strength - Numerical pain rating scale to assess pain intensity - Goniometer to measure range of motion - Fear of movement questionnaire to assess fear of movement

Secondary outcomes

empty

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Pardis Garouee
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
Persons

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
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Person responsible for updating data

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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