

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

Investigate the effect of exercise therapy on knee proprioception in girls with benign hypermobility syndrome aged 18-30 years old

Protocol summary

Study aim

Investigate the effect of exercise therapy on knee proprioception in girls with benign hypermobility syndrome

Design

The sample size was 12 subjects in each group (control and intervention group) and a total of 24 people. The subjects were randomly divided into two groups by block method. The experimental group received exercise for 4 weeks, but the control group did not receive any exercise.

Settings and conduct

This study was conducted in Rehabilitation school of Shiraz University of Medical Sciences and in this regard, two groups (experimental and control groups) were included. In both groups, knee pain, proprioception and quality of life were measured using the VAS, goniometer and SF-36 questionnaire were measured initially and after four weeks of intervention respectively. This study was assessor blinded in a way that the evaluator did not know the nature of the subjects in each group.

Participants/Inclusion and exclusion criteria

Girls with knee pain and benign hypermobility aged 18 to 30 years were included. In the case of people with neurological diseases, other musculoskeletal problems, rheumatoid diseases, osteoarthritis, history of trauma to knee and athlete, were excluded.

Intervention groups

Control and experimental group were considered; The experimental group received exercise for 4 weeks, but the control group did not receive any exercise.

Main outcome variables

Balance; Proprioception

General information

Reason for update

Acronym

BHS

IRCT registration information

IRCT registration number: **IRCT20170619034634N2**

Registration date: **2018-10-28, 1397/08/06**

Registration timing: **retrospective**

Last update: **2018-10-28, 1397/08/06**

Update count: **0**

Registration date

2018-10-28, 1397/08/06

Registrant information

Name

mahnaz daman

Name of organization / entity

shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 5108

Email address

daman@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

shiraz university of medical sciences- rehabilitation school

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

2015-07-23, 1394/05/01

Actual recruitment end date

2015-08-23, 1394/06/01

Trial completion date

empty

Scientific title

Investigate the effect of exercise therapy on knee

proprioception in girls with benign hypermobility syndrome aged 18-30 years old

Public title
Effect of exercise on knee proprioception in girls with benign hypermobility syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having benign hypermobility syndrome Pain in knee
 Female Age range between 18-30 years old
Exclusion criteria:
 Neurological disorders Musculoskeletal disorders
 Rheumatoid diseases and joint inflammatory diseases
 Osteoarthritis ligaments injury Severe trauma to knee
 joint Athlete joint replacement in lower limb

Age
From **18 years** old to **30 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
 Target sample size: **24**
 Actual sample size reached: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization method: limited randomization, block
 Random unit: Individual Considering the presence of two treatment groups in this study (experimental group A, control group B), the size of the blocks was 4. According to the number of samples (24 persons), 6 blocks were determined. 1-AABB 2-ABAB 3-BABA 4-BBAA 5-ABBA 6-BAAB Table of random numbers were used to randomize the blocks.

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants were unaware of which group (control or experiment) were placed

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shiraz University of Medical

Sciences

Street address
Zand street, Central department of Shiraz University of Medical Sciences, Shiraz

City
Shiraz

Province
Fars

Postal code
14336-71348

Approval date
2014-06-22, 1393/04/01

Ethics committee reference number
IR.SUMS.REC.1393.7098

Health conditions studied

1

Description of health condition studied

Benign hypermobility syndrome

ICD-10 code

M35.7

ICD-10 code description

Hypermobility syndrome

Primary outcomes

1

Description

knee proprioception

Timepoint

before and after intervention

Method of measurement

goniameter

Secondary outcomes

1

Description

Pain and quality of life

Timepoint

Before and after intervention

Method of measurement

VAS and SF-36 questionnaire

Intervention groups

1

Description

"Intervention group:" 10 session exercise therapy such as balance and proprioception exercises were performed for participants in intervention group.

Category

Other

2

Description

"Control group:" Did not receive any treatment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation school of Shiraz university of medical sciences

Full name of responsible person

Taghizade Shohreh

Street address

Abivardi 1 street, Chamran Blvd, Rehabilitation school of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3626 5108

Email

Taghizadeh@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor of Research Shiraz University of Medical Sciences

Full name of responsible person

Hashemi Seyed basir

Street address

Zand street, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71 3235 7282

Email

Hashemib@sums.ac.ir

Grant name

Thesis

Grant code / Reference number

92-01-06-7098

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

Yes

Title of funding source

Vice Chancellor of Research Shiraz University of Medical

Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Taghizade Shohreh

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Abivardi 1 street, Chamran Blvd, Rehabilitation school of Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

71947-33669

Phone

+98 71936265108

Fax

Email

Taghizsh@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Taghizadeh Shohreh

Position

Assistant professor

Latest degree

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Other areas of specialty/work

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Fars
Postal code
71947-33669
Phone
+98 71 3626 5108
Fax
Email
Taghizsh@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahnaz daman
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Abivardi 1 street, Chamran Blvd, Rehabilitation school
of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
71947-33669
Phone
+7 136265108
Fax
Email
Daman@sums.ac.ir

Web page address

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

Yes - There is 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

Yes - There is 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

The participants' informed consent form, balance data, proprioception and pain and quality of life are available.

When the data will become available and for how long

The relevant data are available after publication of the study.

To whom data/document is available

All reserchers can use data of this research

Under which criteria data/document could be used

Applicants are also allowed to do other analyzes and study development.

From where data/document is obtainable

The request will be sent to the authors of the email that are listed in the order of priority: Taghizadeh@sums.ac.ir
Hemmatiladan@gmail.com Mahnaz_daman@yahoo.com

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

Send email to authors

Comments