

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effectiveness of group exercise therapy with the instructional pack versus usual physiotherapy programme in improvement of patients with low back pain

Protocol summary

Summary

This study is intended to check the effect of group training and back book compared with routine physiotherapy in chronic low back pain. Patients who are referred to physiotherapy clinics of Semnan university of medical sciences. It is done in a single blind randomized clinical trial method on 70 patients (35 in each group) all the patients are aged between 18- 65 and have suffered pain for at least 3 months. Patients with pain for less than 3 month and patients with medical diseases will exclude. They are placed in 2 groups at random. Data including age, sex, education, occupation, body mass index, history of previous illnesses and treatments is recorded for all patients. The patients in control group will receive routine physiotherapy treatments including Tens, Ultrasound, Hot pack, Laser 3 times a week for 6 weeks. The cases will receive routine physiotherapy treatments and group exercises (1 hour a week) for 6 weeks and a regular walking program (3 times a week). Finally they will be followed up twice. Once after each month following the completion of the treatment. Score of pain (VAS), functional disability (Oswestry questionnaire) , respiratory status (spirometry) and Single limb stance for lumbar position will be evaluated .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041921847N1**

Registration date: **2015-08-31, 1394/06/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-31, 1394/06/09

Registrant information

Name

Armin Sahba

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of group exercise therapy with the instructional pack versus usual physiotherapy programme in improvement of patients with low back pain

Public title

Effectiveness of group exercise therapy with the instructional pack in improvement of patients with low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with mechanical chronic low back pain above 3 months: Male and female age between 18 to 65: Patients without spinal surgery during last year Exclusion criteria: Duration of low back pain under 3 months: History of inflammatory systemic diseases such as Rheumatoid arthritis: History of severe spinal canal stenosis such as Spondylolisthesis and Fibromyalgia: History of cancers or recent radiotherapy and chemotherapy: Pregnancy: Cardiovascular disease: Severe psychiatric diseases: Surgery of spinal cord: Lumbar physiotherapy during recent 6 months: Illiterate patients

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization table of random numbers

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences

City

Semnan

Postal code

Approval date

2015-03-17, 1393/12/26

Ethics committee reference number

93/584659

Health conditions studied

1

Description of health condition studied

chronic low back pain

ICD-10 code

m54.5

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Before treatment and after first and second month of treatment

Method of measurement

Visual analog score

2

Description

Functional disability

Timepoint

Before treatment and after first and second month of treatment

Method of measurement

Oswestry Disability Index Questionnaire

3

Description

respiratory function

Timepoint

Before treatment and after first and second month of treatment

Method of measurement

spirometry

Secondary outcomes

empty

Intervention groups

1

Description

"The intervention group": The intervention group members will receive Usual physiotherapy treatment plus group exercise therapy classes which are held by the physiotherapist twice a week. the walking program commences with 10 minutes walking 4 days a week and will gradually increase up to 30 minutes 5 days a week. The duration of the treatment will be 6 weeks.

Category

Rehabilitation

2**Description**

" Control group: the group which receive usual physiotherapy treatment includes TENS, Ultrasound, Hot pack, Laser and exercise for 6 weeks"

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Aveccina Physiotherapy clinic of Semnan University of Medical Sciences

Full name of responsible person

Armin Sahba

Street address

Aveccina Physiotherapy clinic, Saadi Square, Semnan, Iran

City

Semnan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Semnan University of Medical Sciences

Street address

Vice chancellor for research Semnan University of Medical Sciences, Basij blvd, Semnan, Iran

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

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Physiotherapist

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty