

# 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

Semnan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3335 4180

##### Email address

armin@semums.ac.ir

#### 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**

Armin Sahba

**Position**

Physiotherapist

**Other areas of specialty/work****Street address**

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**Full name of responsible person**

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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*