Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of hypnotherapy with physiotherapy on pain intensity, psychological distress and functional disability among patients with non-specific low back pain

Protocol summary

Summary

Objective the study: The effectiveness of hypnotherapy with physical therapy on pain and functional disability and psychological distress in patients with non-specific low back pain is. Inclusion criteria: age 20 to 45 years; non-specific low back pain by orthopedic specialist, a higher education cycle, with a score of higher than 3 suggestibility suggestibility tests Spiegel. Exclusion criteria: psychotic disorders, lack of participation in the sessions. 30 patients, two groups of intervention and control up to 15 people. Interventions and primary outcomes of the study and its time: In order to control confounding variables before starting treatment, patients are given the option variables such as age and gender as well as education and pain are matched. In the control group only 10 sessions of physiotherapy and hypnotherapy in the intervention group 6 sessions (one session of physical therapy) with 10 sessions of hypnotherapy for 60 minutes before the physiotherapy carried an action plan and run according to the protocols. At its first meeting the required measures are taken to determine the base lines. In the fourth session Surveys conducted for the second time and once again take place at the end of treatment measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011926111N1**
Registration date: **2016-05-01, 1395/02/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-01, 1395/02/12

Registrant information

Name

Nader Abazari

Name of organization / entity

semnan university

Country

Iran (Islamic Republic of)

Phone

+98 21 5514 0585

Email address

abazari@semnan.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-02-09, 1394/11/20

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hypnotherapy with physiotherapy on pain intensity, psychological distress and functional disability among patients with non- specific low back pain

Public title

The effect of hypnotherapy with physiotherapy on pain intensity, psychological distress and functional disability among patients with non- specific low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 20 to 45 years; diagnosed with nonspecific low back pain by orthopedic specialist; a higher education cycle; with a score of higher than 3 suggestibility suggestibility tests Spiegel. Exclusion criteria: psychotic disorders; lack of participation in the sessions.

Age

From **76 years** old to **49 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Semnan University of Medical sciences

Street address

Semnan, Basij Blvd, Semnan University of Medical Sciences

City

Semnan

Postal code

1366757558

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

IR.SEMUMS.REC.1394.128

Health conditions studied

1

Description of health condition studied

Non specific low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

Before intervention, fourth session, after intervention, three mounth after intervention

Method of measurement

Numeric assessment of pain intensity

2

Description

Psychological distress

Timepoint

Before intervention, fourth session, after intervention, three mounth after intervention

Method of measurement

DASS-21

3

Description

Functional disability

Timepoint

Before intervention, fourth session of intervention, after intervention, three mounth after intervention

Method of measurement

Mouris questionair of functional disabiity

Secondary outcomes

empty

Intervention groups

1

Description

Group intervention: 15 people randomly placed in groups. in this Group 6 with 10 sessions of physiotherapy done hypnotherapy session. During the hypnotherapy treatment is performed for 60 minutes before physical therapy. At its first meeting the required measures are taken to determine the base lines. Hypnotherapy session of physiotherapy is executed. Physical therapy and hypnotherapy are operating in accordance with the protocols provided. In the fourth session Surveys conducted for the second time and once again take place at the end of treatment measures.

Category

Diagnosis

2

Description

Control Group: 15 people randomly placed in groups. In this group only 10 sessions of physiotherapy done. Physiotherapy in accordance with the operational

protocols are provided. In the fourth session Surveys conducted for the second time and once again take place at the end of treatment measures.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Clinic of Red Crescent

Full name of responsible person

Dr Atefe Aminianfar

Street address

Mashahir Squer, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Semnan University.

Full name of responsible person

Dr Isagh Rahimian Bouger

Street address

Semnan, Saadi Plaza, Deputy of Research and Technology, Semnan University.

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology, Semnan University.

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

Full name of responsible person

Isagh Rahimian Bouger

Position

PhD in Health Psychology

Other areas of specialty/work

Street address

Semnan

City

Semnan

Postal code

3519899951

Phone

+98 23 3344 8996

Fax

+98 23 3344 8999

Email

are20935@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan university

Full name of responsible person

Nader Abazari

Position

Master student of Clinical Psychology

Other areas of specialty/work

Street address

Semnan university, Darband, Mahdishahr

City

Mahdishahr

Postal code

3519899951

Phone

+98 23 3344 8996

Fax

+98 23 3344 8999

Email

are20935@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Semnan university

Full name of responsible person

Nader Abazari

Position

Master Student of Clinical Psychology

Other areas of specialty/work

Street address

Semnan university, Darband, Mahdishahr

City

Mahdishahr

Postal code

3519899951

Phone

+98 23 3344 8996

Fax

+98 23 3344 8999

Email

are20935@gmail.com

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