

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

The effect of mindfulness based cognitive therapy in addition to stability exercise on disability, fear avoidance beliefs and the thickness of multifidus muscle in the subjects with non specific low back pain

Protocol summary

Study aim

The aim of this study is the effect of mindfulness based cognitive therapy in addition to stability exercise on disability, fear avoidance beliefs and the thickness of multifidus muscle in the subjects with non specific low back pain

Design

The clinical trial with control group, parallel group with 40 patients, randomized

Settings and conduct

40 volunteers with non specific low back pain will be randomly assigned to two intervention group including stability exercise and stability exercise with mindfulness based cognitive therapy

Participants/Inclusion and exclusion criteria

The main inclusion criteria are volunteers aged between 18 and 45 years old and visual analog scale below 4 with non specific low back pain who will be referred to Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences The main exclusion criteria are any systemic diseases, acute musculoskeletal disorders and psychopathy

Intervention groups

Stability exercise will be applied for control group in 3 sessions per week during 8 weeks and stability exercise with mindfulness based cognitive therapy for intervention group in 2 sessions per week during 8 weeks

Main outcome variables

Disability, fear avoidance beliefs and the thickness of multifidus muscle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150602022539N8**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

Ziaeddin Safavi Farokhi

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 23 3365 4180

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zsafavi@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Semnan University of Medical Sciences

Expected recruitment start date

2018-05-19, 1397/02/29

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mindfulness based cognitive therapy in

addition to stability exercise on disability, fear avoidance beliefs and the thickness of multifidus muscle in the subjects with non specific low back pain

Public title

The effect of mindfulness based cognitive therapy in addition to stability exercise in low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Volunteers aged between 18 and 45 years old Visual analog scale below 4 Unilateral or bilateral pain in lumbar area that lasted more than 3 months

Exclusion criteria:

Unwillingness to participate in the project The history of neurological diseases; infection; systemic diseases; surgery of lumbar region; any radicular pain to lower limbs Any structural deformity such as Scoliosis and vertebral bone fracture

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Permuted block randomization
Randomization unit: Person Stratified randomization: Not done
Randomization instrument: Random allocation software (Excel)
Random sequence generation: Used random blocks, each block containing 4 people and allocated a number from 1 to 6 to each block
Allocation concealment: Because of physiotherapy interventions for patients, allocation concealment is not possible

Blinding (investigator's opinion)

Not 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 Semnan University of Medical

Sciences

Street address

Semnan University of Medical Sciences, Kilometer 5 of Damghan Road, Semnan

City

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Province

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Postal code

5319899951

Approval date

2017-10-18, 1396/07/26

Ethics committee reference number

IR.SEMUMS.REC.1396.111

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Disability

Timepoint

Before and immediately after intervention

Method of measurement

Oswestry disability index questionnaire

2

Description

Fear avoidance beliefs

Timepoint

Before and immediately after intervention

Method of measurement

Fear avoidance behavior questionnaire

3

Description

Thickness of multifidus muscle

Timepoint

Before and immediately after intervention

Method of measurement

Millimeter by ultrasonography device

Secondary outcomes

1

Description

Fear of movement

Timepoint

Before and immediately after intervention
Method of measurement
Tampa scale for kinesiophobia questionnaire

2

Description

Cognitive beliefs

Timepoint

Before and immediately after intervention

Method of measurement

Cognitive questionnaire

Intervention groups

1

Description

In the control group stability exercise will be applied in 3 sessions per week during 8 weeks for 20 patient. Lumbar stability exercise will be done 45 minutes per session. The control group will not receive any psychological intervention.

Category

Rehabilitation

2

Description

In the intervention group stability exercise and mindfulness cognitive therapy will be applied in 2 sessions per week during 8 weeks for 20 patient . Mindfulness cognitive therapy will be applied before stability exercise and each intervention will be done 45 minutes per session. The mindfulness cognitive therapy will be done by a psychologist for intervention group and it will be done based on a specific treatment protocol for 8 sessions. The basis of this treatment is relaxation. The focus of this program is on awareness enhancement, attention to cognitive and emotional factors and behavioral activation finally.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neuromuscular Rehabilitation Research Center of Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Street address

Mashahir Square, in front of Helal Ahmar, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Dr Ali Rashidipour

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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

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

Semnan University of Medical Sciences

Full name of responsible person

Ziaeddin Safavi Farokhi

Position

Ph.D, Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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