Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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
Semnan
Province
Semnan
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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Semnan University of Medical Sciences, Kilometer 5 of Damghan Road, Semnan

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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