Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The study of effective of cognitive behavior fear management with stabilization exercise on automatic and voluntary activity of muscles in people with non-specific chronic low back pain

Protocol summary

Summary
Main objective is evaluation of effetive of cognitive behaviour fear management with stabilization exercise on automatic and voluntary activity of muscles in people with non-specific chronic low back pain. This study is a double blinded randomized control trial. Subject with non-specific chronic low back pain of at least 3 mounths duration were randomly assigned to 8 weekly treatments with core stability exercise and cognitive bahavior fear management in groups. Subject will excluded if they have neourological signs from nerve root compression, former back surgery, pregnancy and unsolved social security. Variables are automatic and voluntary activity of abdominal muscles, pain, fear and disability. Testing will be performed prior to intervention and 8 weeks after intervention

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2014020716514N1**
Registration date: **2014-05-31, 1393/03/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2014-05-31, 1393/03/10

Registrant information
Name
Nasim Hemati Broujeni
Name of organization / entity
Semnan University of Medical Science
Country
Iran (Islamic Republic of)
Phone
+98 23 1444 0225
Email address
nhemati@sem-ums.ac.ir

Recruitment status
Recruitment complete
Funding source
Semnan University ofMedical Sciences

Expected recruitment start date
2014-03-01, 1392/12/10
Expected recruitment end date
2014-07-21, 1393/04/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The study of effective of cognitive behavior fear management with stabilization exercise on automatic and voluntary activity of muscles in people with non-specific chronic low back pain

Public title
Effect of cognitive behavior fear management on people with non-specific chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: female with non-specific chronic low back pain for 3 months or more; and pain score of 3 or less on a visual analoge scale. Exclusion criteria: female with neurological signs; breathing problem; arthrities, systemic and metabolic disease; infection; spinal malalignment; former back surgery; pregnancy; vertebral fracture; acute truma; using opiods; unsolved

social security.

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 science

Street address
Vice chancellor for research, Semnan University of Medical Science, Basij Blvd

City
Semnan

Postal code

Approval date
2014-03-05, 1392/12/14

Ethics committee reference number
92/415444

Health conditions studied

1

Description of health condition studied
non-specific chronic low back pain

ICD-10 code
M95, M96,

ICD-10 code description
disorders of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
Automatic activity of muscles

Timepoint
before intervention, 8weeks after interventions

Method of measurement
ultrasound

2

Description
muscle activation

Timepoint
before intervention, 8weeks after interventions

Method of measurement
ultrasound

Secondary outcomes

1

Description
pain

Timepoint
before intervention, 8 weeks after intervention

Method of measurement
visual analoge scale

2

Description
fear of pain

Timepoint
before intervention, 8 weeks after intervention

Method of measurement
Tampa Scale for Kinesiophobia

3

Description
disability

Timepoint
before intervention, 8 weeks after intervention

Method of measurement
Roland and Morris

4

Description
fear of movement

Timepoint
before intervention, 8 weeks after intervention

Method of measurement
Fear Avoidance Belief Questionare

Intervention groups

1

Description
cognotive behavioral therapy is intervention. cognitive behavioral therapy involves a combination of cognitive

and behavioral techniques and is based on the assumption that the individual's way of thinking and affects behavior and emotions. in this cases the idea is to target maladaptive thoughts and behaviors usingstructured technique that aim to identify, challenge, and subsequently change patterns of unhelpful thoughts and behaviors. It gives to pateint once a week for 8 weeks by spesking to pateint.

Category
Behavior

2

Description
core stabilization exercise: the target of these exercise is improvment of muscles activation and increase coordination of those and reduce the copression pressur between joints. it gives 3 times on the week for 8 weeks by therapists

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Neuromuscular Rehabilitation Research Center, Semnan Universityof Medical Science

Full name of responsible person
Nasim Hemati Boroujeni

Street address
Mashahir squar

City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr Raheb Ghorbani

Street address
Vice chancellor for research, Semnan University of Medical Science, Basij Blvd.,

City
Semnan

Grant name

Grant code / Reference number

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

Title of funding source
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
Nasim Hemati Broujeni

Position
MSc student in Physical Therapy

Other areas of specialty/work

Street address
unit 1, code 29, Pirouz alley, up to SeidKhandan bridge, Shariati st, Tehran

City
Tehran

Postal code
1661739634

Phone
+98 21 2287 0910

Fax

Email
nasimhb@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Dr Rosita Hedayati

Position
PhD in Physical Therapy

Other areas of specialty/work

Street address
Vice chancellor for research, Semnan University of Medical Science, Basij Blvd.,

City
Semnan

Postal code

Phone
+98 23 1444 0225

Fax

Email
rosehed@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person

Nasim Hemati Broujeni

Position

MSc student in physical therapy

Other areas of specialty/work

Street address

unit 11, code 29, Pirouz alley, up to Seid Khandan bridge, Shariati st, Tehran

City

Tehran

Postal code

Phone

+98 21 2287 0910

Fax

Email

nasimhb@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