Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of combined pelvic floor treatments on sexual function, pelvic floor muscle strength and endurance in women with chronic low back pain at two different levels of fear of pain

Protocol summary

Study aim

The effect of combined pelvic floor treatments on sexual function, strength and pelvic floor muscle endurance in two groups of women with nonspecific chronic low back pain at two different levels of fear of pain

Design

Clinical Trial, with parallel groups, double-blinded, simple-randomization with random numbers table

Settings and conduct

Volunteers with nonspecific chronic low back pain at IRAN Mehr Physiotherapy Center in shahrood entered the study after completing the consent and demographic form. Then randomly divided into4 groups: high fear of pain and control, low fear of pain and control. The treatment plan includes 10 sessions of combined electromyographic biofeedback, functional electrical stimulation and progressive pelvic floor exercises once a week for a total of three months

Participants/Inclusion and exclusion criteria

Inclusion criteria; Age between 20 and 50 years Having recurrent low back pain for 12 weeks or more VAS less than 3 Sexual dysfunction based on FSFI questionnaire score lower than 26.55 Exclusion criteria; Any symptoms of serious spine involvement Pregnancy Psychological and mental diseases Neurological diseases Respiratory and metabolic diseases Gynecological Diseases

Intervention groups

First group:High fear of pain treated with 10 sessions of combined pelvic floor rehabilitation (electromyographic biofeedback, functional electrical stimulation) with neuro track device and progressive pelvic floor muscle training Second group:Low fear of pain treated with 10 sessions of combined pelvic floor rehabilitation (electromyographic biofeedback, functional electrical stimulation) by neuro track device and progressive pelvic floor muscle training control groups without intervention

Main outcome variables

Pelvic floor muscle strength: Pelvic floor muscles endurance: Female sexual function index questionnaire score: Fear of pain Questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190416043289N2**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

Registration date

2020-01-26, 1398/11/06

Registrant information

Name

MARZIEH MORTEZANEJAD

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3334 0867

Email address

mariptma62@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined pelvic floor treatments on sexual function, pelvic floor muscle strength and endurance in women with chronic low back pain at two different levels of fear of pain

Public title

Pelvic floor treatment on pelvic floor muscle strength

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 20 and 50 years Recurrent low back pain for 12 weeks or more VAS less than 3 Female sexual dysfunction based on FSFI questionnaire score lower than 26.55

Exclusion criteria:

Serious spine involvement Symptoms of the cauda equina syndrome Pregnancy Neurological disorders Mental disorders Respiratory and metabolic diseases Gynecological Diseases

Age

From **20 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with a random number table such that each person is given a code and they are written in a table. we select one place from the table in a blinded manner, then we select 12 numbers smaller than the selected number in the same row. The same would be true for the second treatment and control group

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher will be blind to the intervention using the research assistant and he/she is absent in the treatment room The outcome evaluator will vary with the researcher and research data be given him with code and is unaware of the participants' intervention

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

Headquarters of Semnan University of Medical Sciences,Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2019-12-24, 1398/10/03

Ethics committee reference number

IR.SEMUMS.REC.1398.241

Health conditions studied

1

Description of health condition studied

Chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Strength of pelvic floor muscles

Timepoint

Before and after the end of intervention

Method of measurement

Perinometer setting

2

Description

Endurance of pelvic floor muscles

Timepoint

Before and after the end of intervention

Method of measurement

perinometer setting

3

Description

Score of PASS questionnaire

Timepoint

Before and after the end of intervention

Method of measurement

Questionnaire

4

Description

Score of FSFI (sexual funcion index)questionnaire

Timepoint

Before and after the end of intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: high fear of pain group include biofeedback myoelectric,progressive exercise of pelvice floor muscles,functional electrical stimulation of pelvice floor muscles

Category

Treatment - Devices

2

Description

Intervention group: low fear of pain group include biofeedback myoelectric,progressive exercise of pelvice floor muscles,functional electrical stimulation pelvice floor muscles

Category

Treatment - Devices

3

Description

Control group: no intervention

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranmehr Physiotherapy Center

Full name of responsible person

Maryam mir Abolhasani

Street address

Block 1,4th Floor, Pasargad Doctors Complex,Negarestan Ave,Baghzendan St.,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Marzieh Mortezanejad

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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