

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

**Comparing the effects of stability exercises with general exercises in water, on the cross-sectional area and thickness of the multifidus muscle and the thickness of the transversus abdominis muscle in women with non-specific chronic low back pain.**

### Protocol summary

#### Study aim

The aim of present study is to compare the effect of stabilization exercise with general exercise in water on cross sectional area and thickness of multifiduse and thickness of transversus abdominis muscles and on pain and functional disability in women with nonspecific chronic low back pain.

#### Design

The present randomized controlled trial study is single blind, have two groups: control and experimental including 27 subjects.

#### Settings and conduct

Patients were selected in Shahid Yaheinejad Hospital and after measuring the variables, they entered the swimming pool to perform the intervention and at the end the intervention, relevant variables were measured again.

#### Participants/Inclusion and exclusion criteria

Women with nonspecific low back pain

#### Intervention groups

Experimental group perform the stabilization exercise in water and control group perform general exercise in water.

#### Main outcome variables

Thickness and cross sectional area of the multifidus muscle, thickness of thickness of the transversus abdominis muscle, pain, functional disability

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20221019056245N1**

Registration date: **2023-01-03, 1401/10/13**

Registration timing: **prospective**

Last update: **2023-01-03, 1401/10/13**

Update count: **0**

#### Registration date

2023-01-03, 1401/10/13

#### Registrant information

##### Name

Khodabakhsh Javanshir

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3233 6419

##### Email address

k.javanshir@mubabol.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-01-15, 1401/10/25

#### Expected recruitment end date

2023-05-15, 1402/02/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effects of stability exercises with general exercises in water, on the cross-sectional area and thickness of the multifidus muscle and the thickness of the transversus abdominis muscle in women with non-specific chronic low back pain.

#### Public title

Comparison of the effect of stabilization exercise with general exercise in water on women with chronic nonspecific low back pain

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

woman 25-45 years old chronic low back pain low back pain with instability

##### **Exclusion criteria:**

tumor and cancer epidural abscess spondyloarthropathy osteoporosis spinal fractures deformities inflammatory process disc herniation spondylolysis spondylosis lumbosacral radicular syndrome radiculopathy cauda equina syndrome spinal stenosis previous spinal surgery rheumatic diseases limb discrepancy uncontrolled increased blood pressure heart failure infectious diseases

#### **Age**

From **25 years** old to **45 years** old

#### **Gender**

Female

#### **Phase**

N/A

#### **Groups that have been masked**

- Participant

#### **Sample size**

Target sample size: **27**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

The participants did not know which group they were in.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

##### **Street address**

Ganj afrooz St.

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

4717647745

#### **Approval date**

2020-06-20, 1399/03/31

#### **Ethics committee reference number**

IR.MUBABOL.REC.1399.331

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

nonspecific low back pain

#### **ICD-10 code**

M54.5

#### **ICD-10 code description**

Low back pain

## **Primary outcomes**

### **1**

#### **Description**

Thickness of right and left transversus abdominis muscle

#### **Timepoint**

Before intervention and after intervention

#### **Method of measurement**

Using ultrasonography instrument made by south corea (SONOACE R7-EX)

### **2**

#### **Description**

Thickness and cross sectional area

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Using ultrasonography instrument made by south corea (SONOACE R7-EX)

## **Secondary outcomes**

### **1**

#### **Description**

Functional disability

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Modified Modified Oswestry

### **2**

#### **Description**

Pain

#### **Timepoint**

Before and after intervention

#### **Method of measurement**

Numeric rating scale

## **Intervention groups**

## 1

### Description

Intervention group: Performing stabilization exercise in water based on the protocol

### Category

Rehabilitation

## 2

### Description

Control group: Performing general exercise in water

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid yahyanejad hospital

#### Full name of responsible person

Maede Jarrahi

#### Street address

Shahid mostafa khomini

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Phone

+98 11 2225 0357

#### Email

yahyanejad@mubabol.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Mehdi Rajabnia

#### Street address

Ganj afrooz Street

#### City

Babol

#### Province

Mazandaran

#### Postal code

۴۷۱۷۶-۴۷۷۴۵

#### Phone

+98 11 3219 9592

#### Email

info@mubabol.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Babol 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

Babol University of Medical Sciences

#### Full name of responsible person

Khodabakhsh Javanshir

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

#### Street address

Ganjafrooz street

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#### Province

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#### Phone

+98 11 3219 9592

#### Email

khodabakhshjavanshir@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Khodabakhsh Javanshir

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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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable