

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effects of stabilization exercises focusing on pelvic floor on postnatal Stress urinary incontinence and low back pain

#### Protocol summary

##### Study aim

The aim of this study is to evaluate the effect of stabilization exercises focusing on pelvic floor on stress urinary incontinence and low back pain in postpartum women.

##### Design

Single-blind randomised clinical trial with control group, community-based and pragmatic with parallel groups

##### Settings and conduct

This study was carried out with the participation of 80 women, aged 20 to 45 years old. The presence of SUI and mechanical LBP was verified by a gynecologist and a physiotherapist, respectively. The eligible women were randomly assigned to control and intervention groups using Random Allocation Software (RAS). Allocation was blind and done by a third person. The evaluation was carried out at the beginning and the end of the study by a physiotherapist who was not involved in the research and was blind to allocation. In the intervention group, women participated in a 12-week program that involved performing a home based progressive stabilization exercises focusing on pelvic floor. The control group did not receive any treatment. Place of study: Al-Zahra Hospital in Tabriz

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who lived in Tabriz experienced stress urinary incontinence and back pain after 3-6 months of natural childbirth. Exclusion criteria: Caesarean section; urogenital diseases or infections; receiving other treatments for SUI or back pain; history of pelvic floor or spinal surgeries; malignancies; pelvic or spinal fractures; having twins or multiple children; specific low back pain; severe urinary incontinence.

##### Intervention groups

After initial assessment through the mentioned instruments, women of the intervention group received an exercise program focusing on pelvic floor muscles for 12 weeks. Women in the control group will not receive any treatment.

#### Main outcome variables

Pain; disability; urinary incontinence severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017050618760N4**

Registration date: **2017-06-27, 1396/04/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-11, 1398/01/22**

Update count: **2**

##### Registration date

2017-06-27, 1396/04/06

##### Registrant information

##### Name

Fariba Ghaderi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1333 4647

##### Email address

ghaderif@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

##### Expected recruitment start date

2017-07-06, 1396/04/15

##### Expected recruitment end date

2017-12-21, 1396/09/30

##### Actual recruitment start date

2017-04-04, 1396/01/15  
**Actual recruitment end date**  
2017-12-21, 1396/09/30  
**Trial completion date**  
2017-12-21, 1396/09/30

**Scientific title**  
Effects of stabilization exercises focusing on pelvic floor on postnatal Stress urinary incontinence and low back pain

**Public title**  
Effects of stabilization exercises focusing on pelvic floor on postnatal Stress urinary incontinence and low back pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Women who lived in Tabriz experienced stress urinary incontinence and back pain after 3-6 months of natural childbirth. The urinary incontinence and back pain of pregnancy are those that start during the pregnancy period or after the childbirth.

**Exclusion criteria:**  
Caesarean section urogenital diseases or infections receive other treatments for SUI or LBP history of pelvic floor or spinal surgeries malignancies pelvic or spinal fractures having twins or multiple children specific low back pain severe urinary incontinence LBP or UI before pregnancy

**Age**  
From **20 years** old to **45 years** old

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  

- Outcome assessor

**Sample size**  
Target sample size: **38**  
Actual sample size reached: **40**

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

**Randomization description**  
Randomization will be done through Random Allocation software (RAS).

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Women's assessment at the beginning and end of the study will be conducted by a physiotherapist who is not present in the training process and is blind to women's allocation.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Vice Chancellor for Research of Tabriz University of Medical Science

##### Street address

Tabriz, daneshgah square, tabriz university of medical science

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157635411

#### Approval date

2017-04-24, 1396/02/04

#### Ethics committee reference number

IR.TBZMED.REC.1396.65

## Health conditions studied

### 1

#### Description of health condition studied

Stress urinary incontinence

#### ICD-10 code

N39.3

#### ICD-10 code description

Stress incontinence

### 2

#### 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

Beginning and end of the study with an interval of 12 weeks

#### Method of measurement

Oswestry questionnaire

### 2

#### Description

Pain

### **Timepoint**

Beginning and end of the study with an interval of 12 weeks

### **Method of measurement**

VAS scale

### **3**

#### **Description**

Intensity of stress urinary incontinence

#### **Timepoint**

Beginning and end of the study with an interval of 12 weeks

#### **Method of measurement**

Urinary incontinence questionnaire

## **Secondary outcomes**

### **1**

#### **Description**

strength of pelvic floor muscles

#### **Timepoint**

Beginning and end of the study with an interval of 12 weeks

#### **Method of measurement**

Manual muscle testing

### **2**

#### **Description**

Endurance of pelvic floor muscles

#### **Timepoint**

Beginning and end of the study with an interval of 12 weeks

#### **Method of measurement**

Manual muscle testing

### **3**

#### **Description**

strength of transverse abdominis

#### **Timepoint**

Beginning and end of the study with an interval of 12 weeks

#### **Method of measurement**

Pressure Biofeedback

## **Intervention groups**

### **1**

#### **Description**

Intervention group: women participated in a 12-week program that involved performing a home based progressive stabilization exercises focusing on pelvic floor. The first session was for educating the correct contraction of transverse abdominis muscle using pressure biofeedback and PFM contraction using vaginal examination. Pamphlet and a video CD were given to all participants in this group and the exercises were monitored weekly through telephone interviews. Each

week, permission to start new exercises was given only if the participant had no problem performing the previous exercise.

### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: no treatment

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Al-Zahra hospital in Tabriz

##### **Full name of responsible person**

Fahime Khorasani

##### **Street address**

Tabriz, Baghshomal four-way, Al-Zahra hospital

##### **City**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Mohamad Reza Rashidi

##### **Street address**

Tabriz university of medical science, Tabriz, East Azarbayjan, Iran

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research-vice@tbzmed.ac.ir

#### **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 of Tabriz 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**  
Tabriz university of medical science  
**Full name of responsible person**  
Fahime Khorasani  
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MSC student of physiotherapy  
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Bachelor  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available