# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 linical 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)

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**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

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**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
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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
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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

**Position**

MSC student of physiotherapy

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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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