Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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

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Name of organization / entity
Tabriz University of Medical Sciences

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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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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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Tabriz, Baghshomal four-way, Al-Zahra hospital
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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
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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

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