

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

review to the effect of physiotherapy after childbirth in primigravid women's incontinence and sexual performance

Protocol summary

Study aim

The aim of this study was determine and comparison the results of phisiotherapy after childbirth in women's incontinence and sexual performance .

Design

In this clinical trial, 114 patients with the inclusion criteria were randomly assigned to two parallel groups of 57 (intervention and control).

Settings and conduct

The study population was primigravid women referred to Alzahra and Beheshti hospitals in Isfahan during the years 1397-98. In the control group, routine recommendations after pregnancy get done. Intervention group is referred to the center of the sedighe Tahere once a week for two months in order to perform physiotherapy. Then both intervention and control group are reevaluation after 4 months of childbirth with the completion of two questionnaires.

Participants/Inclusion and exclusion criteria

The inclusion criteria for entering the study were Primigravid, over 8 weeks of natural childbirth, the term baby (top 34 weeks) and healthy, no medical and psychological disease, disuse of alcohol and sexual function drug, disuse of forceps and vacum and exclusion criteria were pregnancy during study, the lack of cooperation to continue physiotherapy, addiction, athletic and suffering from uterine prolaps , cyctocele ,rectocele(grade 3,4).

Intervention groups

In the intervention group, primigravid women are referred to the Sedigeh Tahere center 8 weeks after delivery in order to perform pelvic floor exercise Weekly once for two months at this center for 45 minutes. In the control group, routine postpartum advice is given. Patients in this group received no physiotherapy and finally , after 2 and 4 months, all patients in the study are required to return to the relevant center and complete the questionnaire again.

Main outcome variables

Sexual function ,incontinency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027998N7**

Registration date: **2019-03-13, 1397/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-13, 1397/12/22**

Update count: **0**

Registration date

2019-03-13, 1397/12/22

Registrant information

Name

Maryam Hajhashemi

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-30, 1397/11/10

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

review to the effect of physiotherapy after childbirth in primigravid women's incontinence and sexual performance

Public title

Determine the effect of physiotherapy in women's sexual function and incontinence after first child birth

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Primigravid Over 8 weeks of natural childbirth The term baby (top 34 weeks) and healthy No medical and psychological disease Disuse of alcohol and sexual function drug Disuse of forceps and vacuum

Exclusion criteria:

pregnancy during study The lack of cooperation to continue physiotherapy Addiction Athletic suffering from uterine prolaps , cyctocele ,rectocele(grade 3,4)

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were divided in two groups with simple random sampling.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Central Headquarters, Isfahan University of Medical Sciences and Health Services, Hezar Jereb St.

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Province

Isfahan

Postal code

81746-73461

Approval date

2019-01-30, 1397/11/10

Ethics committee reference number

IR.MUI.MED.REC.1397.194

Health conditions studied**1****Description of health condition studied**

sexual function disorder

ICD-10 code

F52.0

ICD-10 code description

Lack or loss of sexual desire

2**Description of health condition studied**

urinary incontinence

ICD-10 code

N39.4

ICD-10 code description

Other specified urinary incontinence

Primary outcomes**1****Description**

sexual function disorder

Timepoint

2 and 4 months after delivery

Method of measurement

Based on the female sexual function index questionnaire(FSFI)

2**Description**

Fecal and urinary incontinency

Timepoint

2 and 4 months after delivery

Method of measurement

Based on Pelvic Floor Disability Index(PFDI-20) questionnaire

Secondary outcomes**1****Description**

The need for physiotherapy 4 month after delivery

Timepoint

4 month after delivery

Method of measurement

Clinical examination and questioning of the patient's symptoms

Intervention groups

1

Description

Intervention group: In this group, primigravid women are referred to the Sedigheh Tahere center 8 weeks after delivery in order to perform pelvic floor exercise Weekly once for two months at this center for 45 minutes.

Finally, after 2 and 4 months, all patients in the study are required to return to the relevant center and complete the questionnaire again.

Category

Prevention

2

Description

Control group: In the control group, routine postpartum advice is given. Patients in this group received no physiotherapy and finally, after 2 and 4 months, all patients are required to complete the questionnaire.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Maryam Hajihashemi

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Deputy of Research and Technology of Isfahan University of Medical Sciences, Building No. 4, Headquarters, Hezar Jarib Street.

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam al-Sadat Torabipour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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