

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Effect of eight weeks of combined exercises (High intensity interval training and Yuga) on the serum Estradiol and sexual function in postpartum

Protocol summary

Study aim

the effect of High intensity interval training and yoga on the serum levels of Estradiol and sexual function in postpartum women

Design

Two arm parallel group randomized trial and outcome assessment.

Settings and conduct

pregnant mothers who are under vision of health care centers in Bojnourd city with vaginal delivery who are dissatisfied with sexual function compared to pre-pregnancy and delivery. after contacting midwifery clinics, 20 individuals are selected and randomly divided into two groups and familiarization with the research protocol and their consent.

Participants/Inclusion and exclusion criteria

Being primiparous or second-born, being in lactation period, having no specific illness and having a healthy baby. no complications of preterm labor, postpartum depression, no use of vitamin E, no psychotropic drugs, no smoking and alcohol or drugs, no limitation to engage in physical activity and losing more than three sessions. Lack of regular postpartum exercise, normal pre-pregnancy BMI, score of less than 26.5 in the sexual function.

Intervention groups

This study is done on the two experimental and control groups. In EG, each session included 5 to 10 minutes of warm-up program including stretching exercises and then 15-20 minutes of yoga exercises to strengthen the lower limbs and pelvis; as well as several jumping movements. And the explosion is performed optimally for a 2-5 minute increase in heart rate for running (HIIT) training and in the final stage a cooling program is performed for 5-10 minutes with yoga relaxation training. The control group also benefit from routine care.

Main outcome variables

serum Estradiol ; sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170501033743N3**

Registration date: **2021-10-31, 1400/08/09**

Registration timing: **retrospective**

Last update: **2021-10-31, 1400/08/09**

Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

Najmeh Alsadat Shojaeian

Name of organization / entity

Azad University of Bojnourd

Country

Iran (Islamic Republic of)

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+98 58 3222 1594

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-01-21, 1396/11/01

Trial completion date

2018-04-19, 1397/01/30

Scientific title

Effect of eight weeks of combined exercises (High intensity interval training and Yuga) on the serum Estradiol and sexual function in postpartum

Public title

Effect of physical activity on postpartum health

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Being primiparous or second-born Being in lactation (three to four months after childbirth) To have a healthy baby No complications of depression To have a spouse There were also no complications of preterm labor, high blood hypertension in pregnancy, history of liver, kidney, heart, diabetes, inflammatory disease, thrombotic or cerebrovascular diseases, mental illness, hyperlipidemia, atherometrisis, history of chemotherapy, or radiation therapy For the past six months, no hormone replacement therapy, no use of vitamin E, no psychotropic drugs and other effective herbal or chemical drugs No smoking and alcohol or drugs Normal pre-pregnancy BMI

Exclusion criteria:

To have any illness that prevented them from engaging in physical activity To lose the intervention more than three sessions To do the regular exercise in postpartum To gain a score higher than 26.5 based on the sexual function questionnaire. To have any emotional stress such as the death of relatives To decide not to continue in research and/or withdrew her consent

Age

From **21 years** old to **37 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method was used. This method makes the type of intervention assigned to each group completely unpredictable. Therefore, 20 healthy eligible women were divided into control and intervention groups. Random allocation software was used to generate random sequences. In this method, the computer randomly generated the letters A and B. The recipients of letter A joined the intervention group and letter B joined the control group and the allocation ratio of individuals in each group was equal. According to the names of the participants in the study, after obtaining a

random letter by the computer, each letter was assigned to the list of participants in the study and the presence of individuals in the groups was determined. For example, the first letter obtained was given to the first person on the list, and this allocation was applied to the whole list.

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 Islamic Azad university of Bojnourd

Street address

Daneshgah BLV, Islamic Azad university of Bojnourd

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Bojnourd

Province

North Khorasan

Postal code

97796- 94176

Approval date

2017-11-03, 1396/08/12

Ethics committee reference number

34/2412345

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

Effect of physical activities on Estradiol serum and sexual function

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Assessment of sexual function in postpartum

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The main variable of the study was determination of

serum estradiol level. Blood samples from the third to fifth days of menstruation were collected after two months of exercise for the experimental group and the control group by a lab expert through a vein of left hand (05 ml) in a sitting position and they were tested by ELISA method.

Timepoint

After two months of exercise and between third to fifth days of menstruation

Method of measurement

Blood samples from the vein of left hand

2

Description

Before and after two months of intervention, Sexual Function and Sexual Schema Questionnaire(FSFI) was used. This questionnaire measures women's sexual function in six areas including desire, mental stimulation, humidity, orgasm, satisfaction, sexual pain. The questionnaire was developed by Rosen et al. (2000). The FSFI Women's Sexual Function Index in Iran was standardized by Mohammadi and its consistency was obtained by using Cronbach's alpha coefficient ($r = 0.85$) as well as cutoff point for whole scale and subscales.

Timepoint

Before and after the intervention was measured by a questionnaire.

Method of measurement

Sexual Function and Sexual Schema Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each session included 5 to 10 minutes of general warm-up program including stretching exercises and then 15-20 minutes of yoga exercises to strengthen and stretch muscles and body systems, especially the lower limbs and pelvis; as well as several jumping movements. And the explosion was performed optimally for a 2-5 minute increase in heart rate for running (HIIT) training and in the final stage a cooling program was performed for 5-10 minutes with yoga relaxation training. The HIIT exercise was performed so that the subjects ran at a maximum speed of 20 m from the starting point (cone number 1) to cone number two (path A), then turned in the opposite direction, They ran 20 m to cone No. 3 (track B). Finally, return again and run to the starting point (cone number 1) at maximum speed (route C) to complete the 40m distance. Subjects continued this process at maximum speed until the 30-second exercise period was completed. After 30 seconds of rest, the exercise was repeated. Exercise progression was increased by increasing the number of 30-second repetitions from 4 times in the first and second weeks, to 5 times in the third and fourth weeks, and 6 times in the fifth and sixth weeks, and 7 times in

the seventh and eighth weeks

Category

Other

2

Description

Control group: During the 8 weeks of training protocol, the subjects in the control group did not have any regular exercise.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Homa Rahmat Pregnancy Care Center

Full name of responsible person

Mrs Yazdizadeh

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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

Islamic Azad University

Full name of responsible person

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Daneshgah St - Azad University - Department of Sport Sciences

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University of Bojnourd

Proportion provided by this source

10

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Tahereh Shokrani

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Sport physiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

Motor Behavior

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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