

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Breast feeding optimal and neonate's growth after mother aerobic exercise: a randomized controlled clinical trial

Protocol summary

Summary

Aim: The present study aimed to determine the effect of a cycle of aerobic exercise on mother and neonate outcomes. Method and design: This study was a single blind randomized controlled clinical trial, in which patients did not know about their allocation to the study groups and they also did not have access to the other. Sampling method was simple sampling. Subjectives, Inclusion and exclusion criteria: 34 lactating, referring to breast feeding clinic, Isfahan, Iran in 2015-2016 were randomly divided into the intervention and control groups. Inclusion criteria include: non-athletic lactating mothers who feed their baby Exclusively with their milk; 6-8 weeks after delivery; the term infant; the Mother has no activity during the last three months. Major exclusion criteria include: mothers using psychiatric drugs; cigarette; supplementary infant; women with preterm labor. Intervention group subjects were required to do aerobic exercises for six weeks (three days in week for thirty minutes in day). However, mothers in the control group only received the routine care. The main outcome variables in this study were lactation intervals in 24 hours and the weight of newborns, which were measured by lactation questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017071435078N1**

Registration date: **2017-09-17, 1396/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

Name

Akram Amini

Name of organization / entity

Yasuj university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 913 289 9533

Email address

amini@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Yasuj university of medical science

Expected recruitment start date

2016-02-23, 1394/12/04

Expected recruitment end date

2017-02-24, 1395/12/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Breast feeding optimal and neonate's growth after mother aerobic exercise: a randomized controlled clinical trial

Public title

The effect of exercise on lactating

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include: non-athletic lactating mothers who feed their baby exclusively with their milk; 6-8 weeks after delivery; the term infant; the Mother has no activity during the last three months. Major exclusion

criteria include: mothers using psychiatric drugs; cigarette; Supplementary infant; women with preterm labor.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 34

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The one-way blind method was that the research units did not know their allocation to the study groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasuj university of medical science: ethic committee

Street address

Motahari st, Yasuj University of Medical Scienc, Yasuj

City

Yasuj

Postal code

Approval date

2013-11-17, 1392/08/26

Ethics committee reference number

Yums.rec.1391.01

Health conditions studied

1

Description of health condition studied

lactation

ICD-10 code

z39.1

ICD-10 code description

Care and examination of lactating mother

Primary outcomes

1

Description

Neonate weight

Timepoint

At the start of the study and after intervention

Method of measurement

lactation status questionnaire using the interview

2

Description

Breast feeding frequency

Timepoint

At the start of the study and after intervention

Method of measurement

lactation status questionnaire using the interview

Secondary outcomes

empty

Intervention groups

1

Description

Training of aerobic exercise under the supervision of expert then performed. An educational pamphlet of the exercises along with the CD gives them. Those in the exercise group undertook a program of aerobic exercise lasting 30 minutes per day, 3 days per week, for 6 weeks beginning 6 to 8 weeks post partum. The movements of aerobic exercise in each session include a three-step including warm-up, workout and cool down. Three or more days of exercise in any week, an extra week was added to the program. The researcher telephoned the participants to remind them of the timing of the interventions and follow-up.

Category

Other

2

Description

Mothers in the control group only received the routine care

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital, breast feeding clinic

Full name of responsible person

Akram Amini

Street address

Sofeh st, Alzahra hospital, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Yasuj University of Medical Sciences

Full name of responsible person

Dr Hossein Mari Oryad

Street address

Motahari st, Yasuj University of Medical Scienc, Yasuj

City

Yasuj

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, Yasuj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Yasuj university of medical science

Full name of responsible person

Akram Amini

Position

Master of nursing

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty