

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of physical activity during pregnancy on development of Motor, Cognitive and Social skills in infants

Protocol summary

Study aim

The aim of this study was to examine the effects of maternal prenatal selected activities on cognitive, motor, and social development of infants.

Design

Using the G-power software, the sample size was determined and the women in the study were randomly assigned into two experimental (n=20) and control (n=20) groups. According to the considered criteria, the sample size was reduced to 36 pairs (10%).

Settings and conduct

Participants were pregnant women visiting healthcare centers of Bojnourd in 2016-17. In this project, 40 mother-child pairs were evaluated. The participants were recruited by contacting midwives, family education centers or families.

Participants/Inclusion and exclusion criteria

pregnant women

Intervention groups

data were gathered from 40 mother-neonate pairs who were selected from healthcare centers and hospitals (2016-2017) and their infants were evaluated for gross and fine motor skills, cognitive and social skills at ages of 1 and 3 months (final N=36). Pregnant mothers were active in the second and third trimesters. In control group, mothers received the normal medical care.

Main outcome variables

The data from infants were collected in motor, cognitive and social domains during 1 and 3 months of age.

General information

Reason for update

to complete the data

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050133743N1**

Registration date: **2017-05-31, 1396/03/10**

Registration timing: **retrospective**

Last update: **2020-04-15, 1399/01/27**

Update count: **2**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Najmeh Alsadat Shojaeian

Name of organization / entity

Azad University of Bojnourd

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Science and research University of Tehran

Expected recruitment start date

2016-07-20, 1395/04/30

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of physical activity during pregnancy on development of Motor, Cognitive and Social skills in infants

Public title

Effect of physical activity during pregnancy on development of Motor, Cognitive and Social skills in

infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria for the study were: all nulliparous pregnant women; non-athletes and house wives who admitted to city hospitals and prenatal care centers of Bojnurd. They had a gestational age of 23 to 34 weeks and according to their health records, body mass index (BMI) before pregnancy (20 to 24.9 kilograms per square meter) was normal. Similarly they had a normal singleton pregnancy at term (37-41 weeks) with the birth of a healthy baby (without any apparent anomalies). The subjects had no previous history of any underlying disease and were controlled based on their medical records.

Exclusion criteria:

Age

From **22 years** old to **30 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

it allocated participants 1:1 to the experimental (n=20) or the control group (n=20), using a computer random number generator.

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

Islamic Azad University, science and research branch, Tehran

Street address

Sattari highway, Hesarak blvd.

City

بجنورد

Province

North Khorasan

Postal code

۱۴۷۷۸۹۳۸۵۵

Approval date

2016-01-02, 1394/10/12

Ethics committee reference number

15/62125

2

Ethics committee

Name of ethics committee

North Khorasan University of Medical Sciences and Health Services

Street address

South Shariatti St., Karimi Rad Alley

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9413913611

Approval date

2016-02-01, 1394/11/12

Ethics committee reference number

94/60/1883

Health conditions studied

1

Description of health condition studied

Normal pregnancy

ICD-10 code

Z34

ICD-10 code description

Supervision of normal pregnancy

Primary outcomes

1

Description

Motor, Cognitive and Communication Skills

Timepoint

1 and 3 months after delivery

Method of measurement

Ages and Stages III: In this study, Motor development information of infants were obtained by Peabody Development Motor scale (PDMS-2), and cognitive and social development by Ages and Stages Questionnaire (ASQ III) questionnaire. The Peabody Developmental Motor Scales are used to assess the development of motor skills from birth through 5 years. The ASQ Questionnaire is the screening questionnaire of development in five areas of development (gross motor, fine motor, communication, problem solving, and social personal) to assess infants and declares developmental situation compared to the cut-off points. The questionnaire included demographic questions in the first section and in the next section, child development be evaluated with questions and answers "Yes, sometimes, and yet not". The time required to meet 10-15 minutes for the parents. Totally, 30 questions was

intended and for each question, highest score was 10 and 60 for each area. ASQ-3 is reliable and valid. ASQ-3 has excellent sensitivity (0.86) and specificity (0.85) that has adequate accuracy for screening. Strong test-retest reliability of 0.75 to 0.82, inter-rater reliability by comparing the filled-in forms to parents and professional examiners was 0.93.

2

Description

Motor, cognitive and Personal- social skills

Timepoint

1 and 3 months after delivery

Method of measurement

The Peabody Developmental Motor Scales are used to assess the development of motor skills from birth through 5 years. In this study, the gross motor subscales included reflex, stationary, locomotion and fine motor subscales were grasping, and visual-motor integration were used. Each infant's raw scores were eventually turned into standard scores and Development Motor Quotient (DMQ) Ages and Stages III: In this study, Ages and stages Questionnaire III (ASQ 3) was used to evaluate the development rate of Personal- Social skills component in 1 &3 months. The ASQ Questionnaire is the screening questionnaire of development in five areas of development (gross motor, fine motor, communication, problem solving, and social personal) to assess infants and declares developmental situation compared to the cut-off points. The questionnaire included demographic questions in the first section and in the next section, child development be evaluated with questions and answers "Yes, sometimes, and yet not". The time required to meet 10 -15 minutes for the parents. Totally, 30 questions was intended and for each question, highest score was 10 and 60 for each area. ASQ-3 is reliable and valid. ASQ-3 has excellent sensitivity (0.86) and specificity (0.85) that has adequate accuracy for screening. Strong test-retest reliability of 0.75 to 0.82, inter-rater reliability by comparing the filled-in forms to parents and professional examiners was 0.93.

Secondary outcomes

empty

Intervention groups

1

Description

After receiving consent, the experimental group participated from the end of twenty-third week of pregnancy in an intervention period of about 8 weeks with 16 sessions of activity. The activity time was 50 minutes and it was consisted of two parts. The first part includes a 5 minute warm-up, specialized training, such as walking at moderate intensity (60-75 percent of maximum heart rate), massage, relaxation, and 5 minutes of cooling down. In the first part of training time from 25 minutes rose to 40 minutes in the last week. In

the second part 10 minutes of teaching breathing skills and correctly position were taught to them. The selected movements were carried out with the approval of a gynecologist and obstetrician monitoring.

Category

Lifestyle

2

Description

The pregnant women in control group were selected randomly and received usual care during pregnancy. They were not banned from physical activity, but base on their report, they did not follow regular physical activity.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Services center, Kamyab

Full name of responsible person

Dr Esmail Pour

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Emam Khomeini St, Health Services center, Kamyab

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Recruitment center

Name of recruitment center

Bentolhada Hospital

Full name of responsible person

Dr Mafi Nejad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Mohammad Hossein Modaresi

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Najmeh- Alsadat Shojaeian

Position

Motor Development Assistant

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Alzahra University

Full name of responsible person

Masoumeh Shojaei

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Latest degree

Ph.D.

Other areas of specialty/work

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Islamic Azad University, science and research branch of Tehran

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Position

Motor Development Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Trial results

Please tick if results have been published

Yes

Summary result posting date

2020-04-15, 1399/01/27

Table of baseline comparison

Participant flow diagram

Table of variable outcomes' results

Table of adverse events

First publication date

empty

Abstract of published paper

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

to present the data through articles

When the data will become available and for how long

one year later

To whom data/document is available

all people

Under which criteria data/document could be used

to share data

From where data/document is obtainable

Journals

What processes are involved for a request to access data/document

send- referring- publish

Comments