

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The effect of supervised exercise in the prevention of gestational diabetes mellitus in nulliparous women: A randomized control clinical trial

#### Protocol summary

##### Study aim

An Investigation of Sport Intervention in Pregnant Mothers in Pregnant Gestational Disease Prevention

##### Design

This is a randomized, parallel clinical trial study.

##### Settings and conduct

The study will be conducted in Damghan, Iran. Mothers at risk and with gestational diabetes will be detected based on clinical practice guidelines for screening, diagnosis, and treatment before and during pregnancy and after childbirth by Ministry of Health and Medical Education (2019); and having gestational diabetes will be finally approved by a gynecologist. Pregnant mothers introduced by specialist physicians from genealogy offices and clinics, and by midwifery staff at urban health centers will be evaluated by the main researcher in terms of inclusion criteria, nutritional status and physical activity level ( by completing the international Pregnancy Physical Activity Questionnaire (PPAQ) and a Food Frequency Questionnaire (FFQ)).

##### Participants/Inclusion and exclusion criteria

Entrance: pregnant women who have normal fasting plasma glucose in their first pregnancy tests. Exit: one of the obstacles to not doing exercise in pregnancy.

##### Intervention groups

The intervention group will have an exercise intervention program for 8 sessions, 3 sessions per week, each lasting for 45 minutes, and the comparison group will have routine physical activity while receiving routine prenatal care.

##### Main outcome variables

Fasting plasma glucose

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20141001019351N2**

Registration date: **2019-07-02, 1398/04/11**

Registration timing: **prospective**

Last update: **2019-07-02, 1398/04/11**

Update count: **0**

#### Registration date

2019-07-02, 1398/04/11

#### Registrant information

##### Name

Tayebe Zarezade

##### Name of organization / entity

Azad univercity of Damghan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 2523 1711

##### Email address

tayebezarezade@semums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-07-23, 1398/05/01

#### Expected recruitment end date

2019-10-23, 1398/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of supervised exercise in the prevention of

gestational diabetes mellitus in nulliparous women: A randomized control clinical trial

**Public title**

Effect of exercise on preventing gestational diabetes

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

.Healthy pregnancy Normal Fasting plasma glucose in the first weeks of pregnancy Gestational age 18 to 20 weeks to start the plan Mother age 18 to 35 years old A resident of Damghan Control and care of pregnancy in the city of Damghan Contraindications without exercise in Pregnancy Adherence to the implementation of the plan

**Exclusion criteria:**

One of the obstacles to not doing exercise in pregnancy Mother's request to leave the plan at any time

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done after initial registration and obtaining informed consent. Random allocation will be done based on a list obtained from www.Randomization.com. After entering the required information, this website provides two lists of 40 people in two groups of intervention and comparison. At the end of each week, the project secretary will place subjects in the order of entry into the study in the intervention and comparison lists

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This is a parallel randomized clinical trial.

**Secondary Ids**

empty

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

islamic azad university, semnan branch

**Street address**

islamic azad university, damghan branch

**City**

damghan

**Province**

Semnan

**Postal code**

36716 39998

**Approval date**

2018-12-06, 1397/09/15

**Ethics committee reference number**

IR.IAU.SEMNAN.REC.1398.002

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

Gestational diabetes melitus (GDM)

**ICD-10 code**

O00-O08

**ICD-10 code description**

Pregnancy with abortive outcome

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

FPG fasting plasma glucose

**Timepoint**

Week 7 to 10 and 24 to 28 weeks pregnant

**Method of measurement**

Fasting Blood Sampling

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

OGTT(50Glocose)

**Timepoint**

24- 28 gestational age

**Method of measurement**

Blood test

**2****Description**

Pregnant mother weighing

**Timepoint**

The first trimester of gestation, the second trimester of pregnancy, the third trimester of pregnancy, the termination of pregnancy

**Method of measurement**

Weighing scale for adults

**3****Description**

Type of delivery

**Timepoint**

At birth

**Method of measurement**

The case is admitted to the pregnant mother's hospital

**4****Description**

Baby weight

**Timepoint**

The first hour of birth

**Method of measurement**

Baby weighing scale

**5****Description**

Baby's height

**Timepoint**

The first hour of birth

**Method of measurement**

Measuring meter

**6****Description**

Round the head of the baby

**Timepoint**

The first hour of birth

**Method of measurement**

Measuring meter

**7****Description**

Baby's chest

**Timepoint**

The first hour of birth

**Method of measurement**

Measuring meter

**8****Description**

Apgar's first minute baby

**Timepoint**

The first minute of the baby's birth

**Method of measurement**

Apgar score for baby

**9****Description**

Apgar's fifth minute baby

**Timepoint**

The fifth minute of the baby's birth

**Method of measurement**

Apgar score for baby

**10****Description**

Duration of hospitalization

**Timepoint**

From hospital admission to discharge

**Method of measurement**

The case is admitted to the pregnant mother's hospital

**11****Description**

Gestational age at the end of pregnancy

**Timepoint**

At birth

**Method of measurement**

Gestational age based on ultrasound 8 to 10 weeks based on CRL

**12****Description**

Percent oxygen saturation

**Timepoint**

Minutes 1- 2 -3 -4 -5 -10

**Method of measurement**

Baby Oximeter pulse device

**13****Description**

Duration of active phase of labor

**Timepoint**

When admitted to the hospital for termination of pregnancy

**Method of measurement**

Hospital file - Partograph form

**14****Description**

Determining the rate of admission to the hospital after delivery

**Timepoint**

The first 24 hours of birth

**Method of measurement**

Newborn hospital records

**15****Description**

The need for resuscitation measures in the baby

**Timepoint**

Baby birth

**Method of measurement**

Newborn hospital records

**16****Description**

Childbirth injuries

**Timepoint**

The first 24 hours after birth

**Method of measurement**

Newborn hospital records

**17****Description**

Maternal Maternal Injuries

**Timepoint**

The first 2 hours after childbirth  
**Method of measurement**  
Maternity hospital file

velayathos@semums.ac.ir  
**Web page address**  
<https://velayathos.semums.ac.ir/>

## Intervention groups

### 1

#### Description

Intervention group: The intervention group program will be based on the principles of the design of the workout, by specifying the duration, severity, repetition, and type of exercise. The duration of the training in the first week is 60 minutes, in the second week, 100, and the third week, 150, and from the fourth week thereafter, 160 minutes. will be . Exercise intensity throughout the week with moderate intensity and based on the severity of talk test. Repeat the exercise in the first week, 4 times a week, the first two days, 10 minutes and 2 days later, 20 minutes, and from the second week, 5 days a week. Which will be divided according to the timing between days. Types of exercise in the first week, three times a week, once a practice of aerobics and Pilates, and from the second week to two days of walking and three days of aerobic and Pilates exercises during pregnancy. Aerobic exercises include a warming and cooling program and cardio exercises, and Pilates exercises are called seated xercise exercises.

#### Category

Prevention

### 2

#### Description

Control group: Control group can take physical activity while receiving usual care during pregnancy.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Private health clinics and specialized clinics and velayat hospital in Damghan

##### Full name of responsible person

tayebeh zarezadeh

##### Street address

Damghan velayat Hospital

##### City

Damghan

##### Province

Semnan

##### Postal code

3671637881

##### Phone

+98 23 3522 5124

##### Fax

+98 23 3522 5129

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Nematallah Nemati

##### Street address

Islamic Azad University of Damghan Branch

##### City

Damghan

##### Province

Semnan

##### Postal code

3671637849

##### Phone

+98 23 3522 5024

##### Fax

+98 23 3522 5024

##### Email

nnemati258@gmail.com

##### Web page address

<http://www.damghaniau.ac.ir/>

#### Grant name

does not have

#### Grant code / Reference number

ندارد

#### 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

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

Semnan University of Medical Sciences

##### Full name of responsible person

tayebeh zarezadeh

##### Position

phd student

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery  
**Street address**  
Damghan velayat Hospital  
**City**  
Damghan  
**Province**  
Semnan  
**Postal code**  
3671637881  
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velayathos@semums.ac.ir  
**Web page address**  
<https://velayathos.semums.ac.ir/>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
tayebeh zarezadeh  
**Position**  
PHD student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Semnan University of Medical Sciences  
**Full name of responsible person**  
tayebeh zarezadeh  
**Position**  
PHD student

**Latest degree**  
Master  
**Other areas of specialty/work**  
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<https://velayathos.semums.ac.ir/>

## 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

Undecided - It is not yet known if there will be 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

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

### Title and more details about the data/document

IPD: Information and research data Ethic form: Complete the Ethic form by the patient

### When the data will become available and for how long

IPD: 2019 Ethic form: 2019

### To whom data/document is available

IPD: Researcher & Patient Ethic form: Patient

### Under which criteria data/document could be used

IPD: Ethic form: Awareness of test results

### From where data/document is obtainable

IPD: counseling and delivery service of the Avayetavalod

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

IPD: Application form for the researcher and, if agreed, coordinated with the secretary of the design and attendance at the counseling and delivery service of the Avayetavalod

### Comments