

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Design, implementation and evaluation of programs to increase physical activity for mothers who have 1-5 years old children

#### Protocol summary

##### Summary

General Purpose: design, implementation and evaluation of programs to increase physical activity for mothers who have 1-5 years old children in health centers in Isfahan. Design Study: randomized, single blind and multicenter. Target Population: mothers who have 1-5 years old children in health centers in Isfahan. Inclusion Criteria: the mothers under the care who have at least one child 1 to 5 years old; who are not pregnant; have no limitation for doing exercise; are residents of the same area during the performance of the plan. Exclusion Criteria: finding limits for physical activity (such as pregnancy or illness) at the time of plan implementation; in compliance to continue participation in the plan; lack of participation in classes regularly. Sample Size: 166 Intervention: a 4-week intervention program and follow up 1 and 3 months after the start of the project, intervention including a group training session in health care center settings and providing two training booklets for participants. Primary Outcome: the change of physical activity level

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015050722145N1**  
Registration date: **2015-06-03, 1394/03/13**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-06-03, 1394/03/13

##### Registrant information

##### Name

ZahraDana Siadat

##### Name of organization / entity

Isfahnan Univercity of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 8110

##### Email address

z\_dsiadat@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2015-06-05, 1394/03/15

##### Expected recruitment end date

2015-08-06, 1394/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Design, implementation and evaluation of programs to increase physical activity for mothers who have 1-5 years old children

##### Public title

Physicai activity of the mothers who have 1-5 years old children

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion Criteria: the mothers under the care who have at least one child 1 to 5 years old; who are not pregnant; have no limitation for doing exercise; are residents of the same area during the performance of the plan. Exclusion Criteria: finding limits for physical activity (such as pregnancy or illness) at the time of plan implementation; incompliance to continue participation in the plan; lack of

participation in classes regularly.

### Age

From **18 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **166**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Isfahan University Of Medical Sciences

##### Street address

St Hezar jerib, Isfahan University of Medical Sciences and Health Services, Isfahan, Iran

##### City

Isfahan

##### Postal code

81746-73461

#### Approval date

2014-05-28, 1393/03/07

#### Ethics committee reference number

393416

## Health conditions studied

### 1

#### Description of health condition studied

healthy

#### ICD-10 code

XXI

#### ICD-10 code description

Factors influencing health status and contact with health services

## Primary outcomes

### 1

#### Description

physical activity

#### Timepoint

Before intervention and 1 and 3 months after the start project

#### Method of measurement

International physical activity questionnaire (MET-minutes/week)

## Secondary outcomes

### 1

#### Description

Waist circumference

#### Timepoint

Before and 1 and 3 months after the start project

#### Method of measurement

By tape meter(cm)

### 2

#### Description

Hip circumference

#### Timepoint

Before and 1 and 3 months after the start project

#### Method of measurement

By tape meter(cm)

### 3

#### Description

Well being

#### Timepoint

Before and 1 and 3 months after the start project

#### Method of measurement

General health questionnaire-12

### 4

#### Description

Blood pressure

#### Timepoint

Before and 1 and 3 months after the start project

#### Method of measurement

Standard mercury sphygmomanometer(mm/hg)

### 5

#### Description

Body mass index

#### Timepoint

Before and 1 and 3 months after the start project

#### Method of measurement

Weight (using a calibrated scale) and height (by tape meter) as kg/m<sup>2</sup>

## Intervention groups

## 1

### Description

Intervention Group: a one-hour group training session, education of goal setting strategy in a one-hour training session, assessment goal setting forms at four weeks

### Category

Lifestyle

## 2

### Description

Control Group: a one-hour group training session

### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Azadegan health center

##### Full name of responsible person

##### Street address

##### City

Isfahan

### 2

#### Recruitment center

##### Name of recruitment center

Imam Ali health center

##### Full name of responsible person

##### Street address

##### City

Isfahan

### 3

#### Recruitment center

##### Name of recruitment center

4th Imam Ali health center

##### Full name of responsible person

##### Street address

##### City

Isfahan

### 4

#### Recruitment center

##### Name of recruitment center

Amirhamzeh health center

##### Full name of responsible person

##### Street address

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Isfahan University of Medical Sciences

#### Street address

Isfahna Univercity of Medical Sciences, Hezar Jarib, Isfahan, Iran

#### City

Isfahan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

##### Full name of responsible person

jiryae nasrin

##### Position

Resident of Community Medicine

##### Other areas of specialty/work

##### Street address

Isfahna Univercity of Medical Sciences, Hezar Jarib, Isfahan, Iran

##### City

Isfahan

##### Postal code

##### Phone

+98 31 3650 2332

##### Fax

##### Email

n\_jiryae@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Isfahna Univercity of Medical Sciences

##### Full name of responsible person

Jiryae nasrin

##### Position

Resident of Community Medicine

##### Other areas of specialty/work

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**Fax****Email**

n\_jiryae@yahoo.com

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

Isfahna Univercity of Medical Sciences

**Full name of responsible person**

Jiryae nasrin

**Position**

Resident of Community Medicine

**Other areas of specialty/work****Street address**

Isfahna Univercity of Medical Sciences, Hezar Jarib,  
Isfahan, Iran

**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*