

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of education based on the Pender's Health Promotion Model on physical activity of women with type II diabetes

#### Protocol summary

Registration timing: **retrospective**

#### Study aim

Comparison of physical activity , emotion related to physical activity interests barriers & self efficacy perceived interpersonal relationships commitment levels preferences pressing demands in the two

Last update: **2018-07-02, 1397/04/11**

Update count: **0**

#### Registration date

2018-07-02, 1397/04/11

#### Design

The number of 128 patients is entered into the study , using the random permutation block method with the size of block 4 ( using the random permutation table ) into two groups of intervention and random assignment control .

#### Registrant information

##### Name

Soghra Rouholamini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3447 8315

##### Email address

rouholamini.s@ajumas.ac.ir

#### Settings and conduct

Hospital diabetic clinics of Imam Khomeini and Gulistan, 128 women - 30 to 60 years with Type II diabetes , specimens will be studied in accordance with the method of random permutation blocks , with written consent and awareness of confidentiality and purpose of conducting research , according to terms of entry conditions

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

The ability to participate in training sessions , Lack of medical ban on physical activity,Lack Pregnancy Measures of departure Lack of participation in more than one training session Pregnancy during the course of the educational intervention

#### Expected recruitment start date

2018-05-14, 1397/02/24

#### Expected recruitment end date

2018-06-14, 1397/03/24

#### Intervention groups

Education based on the Pender's Health Promotion will be presented for intervention group.

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Main outcome variables

Interests , barriers perceived , related sense of activity , interpersonal relationships , commitment to design , instant

#### Trial completion date

empty

#### General information

#### Scientific title

Effect of education based on the Pender's Health Promotion Model on physical activity of women with type II diabetes

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180514039655N1**

Registration date: **2018-07-02, 1397/04/11**

#### Public title

Education and physical activity in women with type II diabetes

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

The ability to participate in training sessions Having read and write literacy In ahvaz city residence Lack of medical ban on physical activity Lack Pregnancy For at least one year of the diagnosis of the past

### Exclusion criteria:

Lack of participation in more than one training session Pregnancy during the course of the educational intervention

## Age

From **30 years** old to **60 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Randomized

## Randomization description

randomly and according to the permutation block method , which is the size of block 4

## 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

National Ethics Committee in biomedical research

##### Street address

Ahvaz University of Medical Sciences, golestan region

##### City

ahvaz

##### Province

Khouzestan

##### Postal code

6164773748

#### Approval date

2018-05-12, 1397/02/22

#### Ethics committee reference number

ir.ajums.rec.1397.108

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes

#### ICD-10 code

E13

#### ICD-10 code description

Other specified diabetes mellitus

## Primary outcomes

### 1

#### Description

#### Timepoint

#### Method of measurement

### 2

#### Description

Physical activity

#### Timepoint

monthly

#### Method of measurement

Beak's physical activity questionnaire

## Secondary outcomes

### 1

#### Description

Perceived benefits

#### Timepoint

monthly

#### Method of measurement

Investigative - based questionnaire based on improvement of health promotion pattern constructs

### 2

#### Description

Perceived barriers

#### Timepoint

monthly

#### Method of measurement

Investigative - based questionnaire based on improvement of health

### 3

#### Description

Perceived self- efficacy

#### Timepoint

monthly

#### Method of measurement

Investigative - based questionnaire based on improvement of health

#### 4

**Description**

Activity related affect

**Timepoint**

monthly

**Method of measurement**

Investigative - based questionnaire based on improvement of health

#### 5

**Description**

Inter personal influences

**Timepoint**

monthly

**Method of measurement**

Investigative - based questionnaire based on improvement of health

#### 6

**Description**

Situational influences

**Timepoint**

monthly

**Method of measurement**

Investigative - based questionnaire based on improvement of health

#### 7

**Description**

Commitment to a plan of action

**Timepoint**

monthly

**Method of measurement**

Investigative - based questionnaire based on improvement of health

#### 8

**Description**

Immediate competing demands and preferences

**Timepoint**

monthly

**Method of measurement**

Investigative - based questionnaire based on improvement of health

### Intervention groups

#### 1

**Description**

Intervention group: 1- After presenting the necessary explanations to the participants in the study and obtaining informed consent of them , the questionnaires will be placed at the disposal of the two groups . After completing preliminary questionnaires by the participants , the data will be analysed . 2- The training planning is then designed to focus on constructs of improved health promotion and the results of pre - test

data analysis for the test group . 3- Then , 45 minutes training sessions ( two sessions per week ) will be considered for the test group . female control groups also

**Category**

Rehabilitation

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

hospitals diabetes clinics of emam khomeyni & golestan

**Full name of responsible person**

dr. mahin gheybi zadeh

**Street address**

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gheibizadeh-m@ajums.ac.ir

**Web page address**

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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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**

Ahvaz University of Medical Sciences

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

دکتر مهین غیبی زاده

**Position**

Faculty , Faculty of Nursing and midwifery College

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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

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**Full name of responsible person**

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

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**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

**Data Dictionary**

Yes - There is a plan to make this available

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

The total of the potential data is beyond theunstopppable of individuals .

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

Starting accession period 6 months after the results are published

**To whom data/document is available**

It will be available for researchers at academic and academic institutions .

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

in order to investigate the relevant researches

**From where data/document is obtainable**

Email Address

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

For Abstract visit to e - mail and to use this thesis at the Central Library of Tehran University of Medical Sciences .  
**Comments**