

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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

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 .

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

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

Intervention groups

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

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039655N1**

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

Registration timing: **retrospective**

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

Update count: **0**

Registration date

2018-07-02, 1397/04/11

Registrant information

Name

Soghra Rouholamini

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-14, 1397/02/24

Expected recruitment end date

2018-06-14, 1397/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

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

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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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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 theunstopable 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