

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Application of the Health Action Process Approach (HAPA) Theory, on physical activity in patients with type 2 diabetes

Protocol summary

Registration timing: **retrospective**

Study aim

application of HAPA model on the level of physical activity of patients with type 2 diabetes

Last update: **2019-07-15, 1398/04/24**

Update count: **0**

Design

Clinical trials with control group, with parallel groups, stratified randomization, were performed on 109 patients with diabetes (55 interventions and 54 controls), Without blinding, Follow up after three months

Registration date

2019-07-15, 1398/04/24

Settings and conduct

The samples were selected from Diabetes Clinic (Endocrine and Domestic) located in Valiasr Hospital, Zanjan. Four 60-90 minutes training sessions were conducted for the intervention group in a classroom located in Valiasr Hospital. How to intervene using lecture methods, group discussion, question and answer, and providing written instructional materials.

Registrant information

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Name of organization / entity

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Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type 2 diabetes (at least 1 year). Have HbA1c above 7 have enough motivation to change the behavior. Being able to participate and communicate. Exclusion criteria: Not participating in another clinical trial. Not having acute and long-term complications of diabetes preventing their physical activity Not having mental disease Do not use insulin

Recruitment status

Recruitment complete

Funding source

Intervention groups

The intervention group includes patients with type 2 diabetes receiving educational intervention based on the theory of HAPA. The control group includes patients with type 2 diabetes receiving routine care.

Expected recruitment start date

2017-07-22, 1396/04/31

Expected recruitment end date

2017-09-22, 1396/06/31

Actual recruitment start date

2017-07-22, 1396/04/31

Actual recruitment end date

2017-11-01, 1396/08/10

Trial completion date

2017-12-09, 1396/09/18

Main outcome variables

Physical activity; HbA1c

Scientific title

Application of the Health Action Process Approach (HAPA) Theory, on physical activity in patients with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181129041793N1**

Registration date: **2019-07-15, 1398/04/24**

Public title

Application of (HAPA) Theory, on physical activity in Diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

patients with type 2 diabetes (at least 1 year). Have HbA1c above 7 have enough motivation to change the behavior. Being able to participate and communicate. Not participating in another clinical trial.

Exclusion criteria:

Not having acute and long-term complications of diabetes preventing their physical activity Not having mental disease Do not use insulin

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **109**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the eligible individuals, the subjects were grouped according to age and sex and selected according to the ratio of each group among the groups (in the number of samples) (randomized sampling) and with The simple randomized method (using nuts) was divided into intervention and control groups

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

Ethics committee of Zanjan University of Medical Sciences

Street address

Headquarters of Zanjan University of Medical Sciences, Beginning of Islamic Republic Boulevard, Azadi Square

City

Zanjan

Province

Zanjan

Postal code

1998893697

Approval date

2017-04-18, 1396/01/29

Ethics committee reference number

ZUMS.REC.1396.04

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

IV

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

physical activity Walking

Timepoint

Before intervention - three months after the end of the intervention

Method of measurement

IPAQ questionnaire - HAPA questionnaire - Measure the number of steps with a pedometer

Secondary outcomes

1

Description

HbA1c levels

Timepoint

Before the intervention - three months after the intervention

Method of measurement

HbA1c measuring device (Nicokard)

Intervention groups

1

Description

Intervention group: The intervention group was received a theory-based four educational sessions (lasted 60-90 minutes) according to the HAPA model constructs (self-efficacy, risk perception, outcomes expectation , Action Plan), and a physical activity programme.

Category

Lifestyle

2

Description

Control group: The control group was received a educational leaflet on diabetes and physical activity.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Social Determinants of Health Reserach Center

Full name of responsible person

Dr. Masoumeh Namadian

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Hospital of Valiasr Hospital, above Valiasr Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Masoumeh namadian

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Community Health

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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

Health Promotion

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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

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Part of the participants information, including demographic characteristics and disease information after making anonymous of private information, methodology and results will be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researcher team

Under which criteria data/document could be used

Observe the principles of trustee and insert the name of the researcher in the articles used in this research.

From where data/document is obtainable

Central Library of Zanjan University of Medical Sciences

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

Send an email to the researcher

Comments

This project is A master student thesis, and if accepted in journals, its results will be published in the form of a paper