Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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

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

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.

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

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.

Main outcome variables
Physical activity; HbA1c

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181129041793N1**
Registration date: **2019-07-15, 1398/04/24**
Registration timing: **retrospective**

Last update: **2019-07-15, 1398/04/24**
Update count: **0**

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

Registrant information

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Maedeh Ghobadian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

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

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

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
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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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Health Promotion

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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
Researche 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