

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of educational program based on the Health ActionProcess Approach Model on consumption of fruit and vegetable in type 2 diabetes patients in Buin Zahra city.

Protocol summary

Study aim

Design, implementation and evaluation of health approach education that can improve the quality of life of diabetic patients.

Design

From among the centers covered in the city, four centers will be selected by lottery, and in these four centers, after the entry and exit conditions, the participants in the study will be selected by simple randomization and will be divided into two intervention and control groups. This study will be done on 100 people.

Settings and conduct

This study will be conducted in Buin Zahra city of Qazvin province and regarding the consumption of fruits and vegetables in diabetic patients.

Participants/Inclusion and exclusion criteria

Entry requirements: Having type 2 diabetes, being a volunteer. Age between 30 and 60 years. Not having complications of diabetes, having a mobile phone, being literate, suffering from the disease for one year. Exit conditions: Reluctance to participate in the study, having physical and mental disorders, participation in another study, immigration, complications of diabetes, addiction.

Intervention groups

The educational intervention includes a group training program that is presented by the researcher in four sessions for 30-35 minutes. The training will include lectures, slides, film and photo shows, group discussions, brainstorming, and questions and answers. For the control group, after completing the questionnaire in the second stage, a training session will be held and a training package including pamphlets, training videos and posters will be provided to them.

Main outcome variables

Amount of fruit and vegetable consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221224056911N1**

Registration date: **2023-09-18, 1402/06/27**

Registration timing: **retrospective**

Last update: **2023-09-18, 1402/06/27**

Update count: **0**

Registration date

2023-09-18, 1402/06/27

Registrant information

Name

Yahya Ghasemkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3422 4170

Email address

y.ghasemkhani@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational program based on the Health ActionProcess Approach Model on consumption of fruit and vegetable in type 2 diabetes patients in Buin Zahra city.

Public title

The effect of educational program based on the Health ActionProcess Approach Model on consumption of fruit and vegetable in type 2 diabetes

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes. Being a volunteer Being between 30 and 60 years old Not having complications related to diabetes The patient has a smart mobile phone Be literate in reading and writing A history of diabetes for at least one year.

Exclusion criteria:

Suffering from physical and mental illnesses Having severe complications of diabetes Having an addiction to drugs, alcohol, etc.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Buin Zahra city includes 11 comprehensive health service centers, out of which four centers will be selected by lottery, and then the names of the patients will be extracted and a list will be prepared, and those who do not have the conditions to participate in the study will be removed from the list. Among the remaining patients, people will be selected and entered into the study in a simple way (by lottery). Also, 12 people will be allocated to the intervention group and 12 people to the control group from two centers, and 13 people will be allocated to the intervention group and 13 people to the control group from the other two centers.

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 Qazvin University of Medical Sciences

Street address

No. 18, Elaheh Ave.14 , governorship Blvd., Buin Zahra Town

City

Buin Zahra

Province

Qazvin

Postal code

3451746338

Approval date

2023-03-18, 1401/12/27

Ethics committee reference number

IR.QUMS.REC.1401.367

Health conditions studied

1

Description of health condition studied

Status of fruit and vegetable consumption in diabetic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Amount of fruit and vegetable consumption

Timepoint

Before the educational intervention and one month after the educational intervention

Method of measurement

According to the self-reported questionnaire by the diabetic patients participating in the study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, after completing the questionnaire and according to the results of the analysis of the path and weight of each structure and according to the standard time of a training session which is 30 to 45 minutes and will be implemented based on the training goals. In these sessions, the food pyramid and Food groups including fruits and vegetables, the benefits of consuming fruits

and vegetables, alternative behaviors will be presented through group discussion, existing obstacles will be removed by the method of brainstorming and verbal encouragement of patients, the positive experiences of patients following a diet containing fruits and vegetables. It will be discussed in a group, strategies for increasing access to fruits and vegetables, preparing a meal containing fruits and vegetables, and preparing a snack such as a fruit and vegetable salad will be taught. Also, a video on how to clean and disinfect fruits and vegetables will be taught. It will be distributed to patients.

Category

Behavior

2

Description

Control group: For the control group, no special program or intervention will be considered, but in order to comply with the ethics of the research, after the final evaluation (FOLLOW UP), a group training session will be considered for all patients of the control group, and also, the training package developed in The choice of all patients and the control group will be included.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Rural Urban Service Centers of Buin Zahra City

Full name of responsible person

Yahya Ghasemkhani

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No. 18, Elaheh Ave.14 , governorship Blvd., Buin Zahra Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi Mir Hashemi

Street address

Deputy of Research and Technology Qazvin University of Medical Sciences p. 18, Modt Sub, Shahid Beheshti Blvd, Qazvin city

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sm.mirhashemi@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Yahya Ghasemkhani

Position

High school

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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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

All information about the main outcome can be shared.

When the data will become available and for how long

The access period will start 6 months after the results are published.

To whom data/document is available

All researchers working in academic and industrial institutions can receive it.

Under which criteria data/document could be used

In case of confidentiality, patient information and study results should be used to improve patients' quality of life.

From where data/document is obtainable

Email address:y.ghasemkhani60@gmail.com Phone number:02834224170 Yahya Ghasemkhani

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

1- Submitting an application on behalf of the applicant.
2- I received the request. 3- Sending documents to the applicant. About 2 weeks.

Comments