

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effectiveness of online educational lifestyle intervention in the elderly with type 2 diabetes in Qazvin

Protocol summary

Study aim

Determining the effectiveness of online educational lifestyle intervention in the elderly with type 2 diabetes in Qazvin

Design

In order to select the samples and assign the samples to the experimental and control groups in the current study, first the research license code will be issued from the active health centers (13 health centers), 2 health centers will be selected randomly. Then, a list of all the elderly covered by the centers who actively refer to receive services and those who have a family file in the apple system will be prepared. They will then be invited to participate in the research by calling them and introducing the research and its objectives. Then, randomly in each center, if the participants are ready, one will be assigned to the control group and the other to the intervention group. After announcing the readiness of the elderly, based on a timetable, they are invited to either attend the health centers in person or, if they wish, to complete the online questionnaire online in the first phase.

Settings and conduct

Research population In the present study, all the elderly will be covered by urban health centers in Qazvin.

Participants/Inclusion and exclusion criteria

1. Voluntary and informed participation
2. Age over 65 years
3. Literacy
4. Ownership and ability to use an Android mobile phone or iOS system (the elderly person or a family member who is in regular contact with him).
5. No smoking and alcohol
6. No cancer

Intervention groups

Research population In the present study, all the elderly will be covered by urban health centers in Qazvin. We give a questionnaire to the elderly before training and we give a questionnaire after training to assess.

Main outcome variables

Perceived risk Efficacy Awareness Waiting for the outcome Action planning Be able to plan social support

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210509051229N1**

Registration date: **2022-08-30, 1401/06/08**

Registration timing: **retrospective**

Last update: **2022-08-30, 1401/06/08**

Update count: **0**

Registration date

2022-08-30, 1401/06/08

Registrant information

Name

Fateme Zanjanchi Nikoo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3369 7495

Email address

f.zanjanchinikoo@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-07-01, 1400/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of online educational lifestyle intervention in the elderly with type 2 diabetes in Qazvin

Public title

The effectiveness of online educational lifestyle intervention in the elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Literacy of reading and writing Ownership and ability to use Android mobile or IOS system People with diabetes Voluntary and conscious participation of people

Exclusion criteria:

Suffering from physical diseases or mental disorders that prevent proper and regular participation in any way be in research Lack of access to the Android system and software related to What's App Unwillingness to cooperate in further research

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 130

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a multi-stage randomization method was used. So that 130 elderly people with diabetes are needed to conduct the research and there should be 65 people in each control and experimental group. At first, 4 centers were randomly selected from 13 existing health centers in Qazvin city. Then, among these 4 centers, the number of elderly people with diabetes was removed, and among all the elderly people, by random method and using the number of 130 cards, 65 control groups and 65 experimental groups were selected. and then that card was discarded. Finally, after dividing the people into two groups, the questionnaires were completed.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

In this study, a questionnaire is given to individuals before training and a questionnaire is filled out once after training. This study is performed in two groups of control and intervention.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Qazvin university of medical sciences

Street address

Shahid Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Approval date

2021-04-19, 1400/01/30

Ethics committee reference number

IR.QUMS.REC.1400.029

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Healthy lifestyle in diabetics

Timepoint

Before training-After training

Method of measurement

In this study, the questionnaire is the measurement scale. The questionnaire questions include the following: 1- Demographic information 2- Lifestyle questionnaire: This 19-item questionnaire was designed by Lipke and Zigelman in 2006. All questions in the questionnaire are scored on a Likert scale from one to four (completely false = 1 to completely true = 4). 3-Physical Activity Questionnaire: International Physical Activity Questionnaire, as an international physical activity measurement tool in Geneva by WHO. and CDC (1998) was suggested for the age group of 69-15 years. There are two forms of IPAQ 4- Health Action Questionnaire: Perceived Risk Questionnaire: (includes 6 questions related to physical activity and regular consumption of fruits and vegetables) - Self-efficacy scale: (includes 6 questions related to self-efficacy and with a 5-point Likert scale E) - Awareness scale: (yes-no answer options) - Outcome expectation scale: (the scale consists of 5 questions and with 5-point answer options) - Action planning scale - Coping plan scale - Support scale social

2

Description

The main variable measured in this study is lifestyle items.

Timepoint

Before training-After training

Method of measurement

HAPA Questionnaire

3

Description

The main variable measured in this study is lifestyle items.

Timepoint

Before training-After training

Method of measurement

Nutrition Questionnaire -

Secondary outcomes

1

Description

Average perceived risk--

Timepoint

people are divided into two categories of control and intervention and are compared with each other.

Method of measurement

Knowledge-Nutrition-HAPA Questionnaire

2

Description

Average awareness-Self

Timepoint

people are divided into two categories of control and intervention and are compared with each other.

Method of measurement

Knowledge-Nutrition-HAPA Questionnaire

3

Description

efficacy-Expectation of outcome

Timepoint

people are divided into two categories of control and intervention and are compared with each other.

Method of measurement

Knowledge-Nutrition-HAPA Questionnaire

4

Description

Social support

Timepoint

people are divided into two categories of control and intervention and are compared with each other.

Method of measurement

Knowledge-Nutrition-HAPA Questionnaire

Intervention groups

1

Description

Intervention group: During 8 weeks, the intervention group receives training on the correct methods of food intake in people with diabetes, the effect of physical activity in controlling diabetes, and the consumption of fruits and vegetables in people with diabetes, and after 3 months of The last retraining session of the questionnaire is given to two experimental and control groups to answer the questions.

Category

Lifestyle

2

Description

In the control group, at first, the questionnaire is completed by elderly people with type 2 diabetes. And after 3 months, when the relevant training were passed to the intervention group, the questionnaires will be completed again in the two groups to measure the result and impact of the training in the two groups. Finally, training and explanations about lifestyle, physical activity and food in people with diabetes are also given to the control group so that they do not benefit from the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers

Full name of responsible person

Alireza Mehralian

Street address

Shahid Babayi St

City

qazvin

Province

Qazvin

Postal code

63111-34147

Phone

+98 28 3365 2972

Fax

+98 28 3365 8060

Email

infobhc@qums.ac.ir

Web page address

<http://shbhc.qums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Peyman Namdar

Street address

Shahid Bamonar

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Fax

+98 28 3335 5162

Email

info@qums.ac.ir

Web page address

<http://www.qums.ac.ir/portal/home>

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

Isa Mohammadi Zeidi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Shahid Bamonar Blvd

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Fax

+98 28 3335 5162

Email

imohammadi@qums.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Fateme Zanjanchi Nikoo

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Hakim Blvd

City

Qazvin

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Fax

+98 28 3335 5162

Email

f.zanjanchinikoo@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Fateme zanjanchi Nikoo

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

Hakim Blvd

City

قزوین

Province

Qazvin

Postal code

15315-34199

Phone

+98 28 3333 6001

Fax

+98 28 3335 5162

Email

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

Some of the data related to the main outcome can be shared

When the data will become available and for how long

Access starts 6 months after the results are published.

To whom data/document is available

Data is confidential.

Under which criteria data/document could be used

The data are examined for analysis.

From where data/document is obtainable

Fateme Zanjanchi Nikoo

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

Data is confidential

Comments