

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Educational Intervention Based on Transtheoretical Model on Self-care Behavior In Women With Type 2 Diabetes At Qazvin City In 1392

Protocol summary

Summary

This Randomized Controlled Trial aims to Evaluate the Effectiveness of Interventions Based on Transtheoretical Model on Womens Self-care Behavior With type 2 Diabetes in Qazvin. Inclusion Criteria: Diabetes; 60 years of age ;a Willingness to Participate in the Study; Reading and Writing; Having not acute or Chronic Disease other than Diabetes or a Prescribed Diet which Prevents them of Physical activity or Consumption of Fruits and Vegetables; the lack of advanced complications from diabetes and taking sedatives or other medications; And Exclusion criteria: absence of more than two Intervention sessions; not wanting to continue to Contribute ; to cause trouble or Inconvenience During the Intervention. Population sample :Women with Type 2 Diabetes and Sample size is 96 patients in the two Groups are equal . From Two Health centers in which the screening of Diabetes is done,Randomly assigned to a Treatment center and the other as a Controller are Selected. 48 people are Randomly selected at each center. Data were Collected using a Questionnaire based on Transtheoretical Model and Blood tests (HBA1C).Questionnaire will be distributed to Two times, before and Three Months after the End of the Intervene and Blood tests will done. In the Experimental group, the Intervention will be assessed model-based Intervention and control group not receiving the Intervention. At the End of the study ,Effect of Intervention will be Determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071514010N1**

Registration date: **2014-01-02, 1392/10/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-02, 1392/10/12

Registrant information

Name

Maryam Zavar Mogaddam

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 2256 4080

Email address

m.zavartoosi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Guilan University Of Medical Sciences

Expected recruitment start date

2013-05-28, 1392/03/07

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Educational Intervention Based on Transtheoretical Model on Self-care Behavior In Women With Type 2 Diabetes At Qazvin City In 1392

Public title

Effect of Intervention on Diabetes selfcare

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Diabetes; 60 years of age; a Willingness to Participate in the Study; Reading and Writing; Having not Acute or Chronic disease other than diabetes or a prescribed diet Which prevents them of Physical activity or Consumption of Fruits and Vegetables; The lack of Advanced Complications from Diabetes and Taking Sedatives or other Medications
Exclusion Criteria: Absence of More than Two Intervention Sessions; not wanting to Continue to Contribute; to Cause trouble or Inconvenience during the Intervention.

Age

To 59 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 96

Randomization (investigator's opinion)

Randomized

Randomization description

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

Guilan University Of Medical Sciences

Street address

Martyr Siadati Street, Namjoo Street

City

Rasht

Postal code

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

4920101214

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

HBA1C

Timepoint

Before Intervention and 3 Months After Intervention

Method of measurement

Blood Tests

2

Description

Fruit and Vegetable Consumption

Timepoint

Before and Three Months after Education

Method of measurement

Sheet Report

3

Description

Physical Activity

Timepoint

Before and Three Months after Education

Method of measurement

GPAQ Questionnaire

Secondary outcomes

1

Description

Transtheoretical Model Structurs for Fruit and Vegetable Consumption

Timepoint

Before and Three Months After Intervention

Method of measurement

Model-based Questionnaire

2

Description

Transtheoretical Model Structurs for Physical Activities

Timepoint

Before and Three Months After Intervention

Method of measurement

Model-based Questionnaire

Intervention groups

1

Description

Intervention Based on Transtheoretical model to Improve Diabetic Women Self-care Behaviors In the Intervention Group .

Category

Prevention

2

Description

The control group did not receive the intervention and at the end, training package provide them .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Tagavi Health Center

Full name of responsible person

Ms. Homayounfar

Street address

Dehkhoda Square

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Rabi Ullah Farmanbar

Street address

Department of Health, Siadati Street , Namjoo Street -

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Maryam Zavarmogaddam

Position

MSc in Health Education

Other areas of specialty/work

Street address

Mohammadih

City

Qazvin

Postal code

3491737445

Phone

+98 28 1256 4080

Fax

Email

m.zavartoosi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Rabiollah Farmanbar

Position

PhD in Health Education

Other areas of specialty/work

Street address

Department of Health of Guilan University of Medical Sciences Building , In front of Azodi Stadiums , Namjoo Ave , Rasht

City

Rasht

Postal code

3391

Phone

+98 13 1555 3202

Fax

+98 13 1323 4155

Email

farmanbar@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Maryam Zavarmogaddam

Position

MSc in Health Education

Other areas of specialty/work

Street address

Mohammadih

City
Qazvin
Postal code
Phone
00
Fax
Email
m.zavartoosi@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty