

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The Effect Of Self-Management On Self-Efficacy And Quality Of Life Related To Oral Health In Patients With Type 2 Diabetes

Protocol summary

Study aim

Determining the effect of self-management on self-efficacy and quality of life related to oral and dental health of people with type 2 diabetes

Design

This study will be a double-blind clinical trial on 70 patients with type 2 diabetes. The samples will be assigned to intervention and control groups by block randomization method.

Settings and conduct

This study will be a double-blind clinical trial on 70 patients with type 2 diabetes. The place of implementation of the study will be the Diabetes Clinic of Taraba Hospital. The samples will be assigned to intervention and control groups by block randomization method. The control group will receive the common trainings of the diabetes clinic, but in the intervention group, 12 sessions of self-management training based on the 5-step model A will be conducted for 12 weeks and each session will last 30 to 45 minutes.

Participants/Inclusion and exclusion criteria

Entry requirements: 1. Patients with type 2 diabetes (at least 3 to 6 months have passed since the definitive diagnosis of type 2 diabetes) 2. Age range from 20 to 70 years 3. Proficiency in Persian language 4. Having hearing and sight 5. Not suffering from mental illnesses or using psychoactive drugs 6. Willingness to participate in the study Non-entry conditions: 1. Unwillingness to participate in the study 2. Participation in self-management courses

Intervention groups

The control group will receive the common trainings of the diabetes clinic, but in the intervention group, 12 sessions of self-management training based on the 5-step model A will be conducted for 12 weeks and each session will last 30 to 45 minutes.

Main outcome variables

Self-Efficacy And Quality Of Life Related To Oral Health

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220709055421N2**

Registration date: **2023-01-05, 1401/10/15**

Registration timing: **prospective**

Last update: **2023-01-05, 1401/10/15**

Update count: **0**

Registration date

2023-01-05, 1401/10/15

Registrant information

Name

Mahtab Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3505

Email address

m.farahani@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-24, 1401/11/04

Expected recruitment end date

2023-04-24, 1402/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Self-Management On Self-Efficacy And Quality Of Life Related To Oral Health In Patients With Type 2 Diabetes

Public title

The effect of self-management on the oral and dental health of patients with diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with type 2 diabetes (at least 3 to 6 months have passed since the definitive diagnosis of type 2 diabetes) Age range from 20 to 70 years Proficiency in Persian language Having hearing and sight Not suffering from mental illnesses or using psychoactive drugs Willingness to participate in the study

Exclusion criteria:

Unwillingness to participate in the study Participation in self-management courses

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by available method, and if the research samples are eligible to participate in the study, they will be placed in one of the test or control groups by random blocks of four (A, A, B, B). Code A will be assigned to the intervention group and code B will be assigned to the control group

Blinding (investigator's opinion)

Double blinded

Blinding description

Since the researcher will perform the intervention and another colleague will collect the data, and also considering that the person who will also perform the data analysis will not know about the codes assigned to the patient, this study is It will be double-blind.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Arak University of Medical Sciences

Street address

Alam El Hadi St., Shahid Shiroudi St

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2022-11-20, 1401/08/29

Ethics committee reference number

IR.ARAKMU.REC.1401.241

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

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Self-Efficacy Related To Oral Health

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Oral and dental health self-efficacy questionnaire OHSQ

Secondary outcomes**1****Description**

Quality Of Life Related To Oral Health

Timepoint

Before the start of the intervention and after the end of the intervention

Method of measurement

Quality of life questionnaire related to oral health (OHIP-14)

Intervention groups

1

Description

Intervention group: In the intervention group, 12 sessions of self-management training based on the 5-step model A will be conducted for 12 weeks, each session lasting 30 to 45 minutes.

Category

Lifestyle

2

Description

Control group: The control group will receive the common trainings of the diabetes clinic.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان طرفه

Full name of responsible person

محمدعلی مردم

Street address

in front of Islamic Propaganda Organization., Ibn Sina St., Baharestan Square., Torfe hospital

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Arak University of Medical Sciences

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Alam El Hadi St., Shahid Shiroudi St

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Web page address

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

MohammadAli Mardom

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Arak University of Medical Sciences

Full name of responsible person

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Associate Professor

Latest degree

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information and results will be published in the form of articles.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available