

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the Effectiveness of Face-To-Face and Non-Face-To-Face Training on Oral and Dental Health Behaviors Based On the Health Belief Model in Patients with Type 2 Diabetes Referring To Comprehensive Rural Health Service Centers, Andimeshk, Iran

Protocol summary

Study aim

Comparing the Effectiveness of Face-To-Face and Non-Face-To-Face Training on Oral and Dental Health Behaviors Based On the Health Belief Model in Patients with Type 2 Diabetes Referring To Comprehensive Rural Health Service Centers

Design

One hundred twenty patients with type 2 diabetes were selected based on the inclusion criteria and then were randomly divided into two face-to-face (60 patients) and non-face-to-face (60 patients) training groups. For the face-to-face training group, training programs will be through lectures with questions and answers, group discussions, and videos in three 60-minute sessions; and for the non-face-to-face training group through the presentation of patient education pamphlets.

Settings and conduct

comprehensive rural health service centers in Andimeshk

Participants/Inclusion and exclusion criteria

The inclusion criteria were confirming the diagnosis of type 2 diabetes, having literacy, having age 30-65 years, enjoying physical and mobility ability, not having artificial teeth, not suffering from severe mental illnesses and exclusion criteria consisted of having no consent to participate in the study and being absent in more than two intervention sessions.

Intervention groups

face-to-face training group: It included lecture methods with questions and answers, group discussion, playing training clips, and using training aids (such as slides and video projectors) in three 60-minute sessions

Main outcome variables

Increasing awareness Performing preventive behaviors against oral and dental diseases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160418027449N7**

Registration date: **2022-10-08, 1401/07/16**

Registration timing: **retrospective**

Last update: **2022-10-08, 1401/07/16**

Update count: **0**

Registration date

2022-10-08, 1401/07/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 372510015

Email address

trakhshani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-01, 1401/05/10

Expected recruitment end date

2022-09-01, 1401/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Effectiveness of Face-To-Face and Non-Face-To-Face Training on Oral and Dental Health Behaviors Based On the Health Belief Model in Patients with Type 2 Diabetes Referring To Comprehensive Rural Health Service Centers, Andimeshk, Iran

Public title

Comparing the Effectiveness of Face-To-Face and Non-Face-To-Face Training on Oral and Dental Health Behaviors Based On the Health Belief Model in Patients with Type 2 Diabetes Referring To Comprehensive Rural Health Service Centers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

confirming the diagnosis of type 2 diabetes having literacy having age 30-65 years enjoying physical and mobility ability not having artificial teeth not suffering from severe mental illnesses

Exclusion criteria:

having no consent to participate in the study being absent in more than two intervention sessions

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. At first, the list of all qualified people is prepared, we number them. Then they will be divided into two experimental and control groups by random allocation method using a table of random numbers.

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 Shiraz University of Medical

Sciences

Street address

Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-07-27, 1399/05/06

Ethics committee reference number

IR.SUMS.REC.1399.637

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Preventive behaviors of oral and Dental diseases

Timepoint

Two stages before and two months after the training intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It included lecture methods with questions and answers, group discussion, playing training clips, and using training aids (such as slides and video projectors) in three 60-minute sessions. The face-to-face training group was divided into four 15-subject groups to facilitate the transfer of materials and the opportunity for more interaction between the trainer and the patients.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadi Comprehensive Rural Health Center
Full name of responsible person
 Azita Rahmati
Street address
 Azadi Comprehensive Rural Health Center
City
 Andimeshk
Province
 Khuzestan
Postal code
 1111111111
Phone
 +98 901 589 2517
Email
 rahmati_a@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Tayyibah Rakhshani
Street address
 Vice-Chancellor for Research, Shiraz University of
 Medical Sciences, Zand Blvd.
City
 Shiraz
Province
 Fars
Postal code
 7134814336
Phone
 +98 71 3230 5410
Email
 Trakhshani@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
 Shiraz University of Medical Sciences

Full name of responsible person

Azita Rahmati

Position

دانشجو

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Province

Khuzestan

Postal code

1111111111

Phone

009015892517

Email

rahmati_a@ajums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Shiraz University of Medical Sciences

Full name of responsible person
 Tayyibeh Rakhshani

Position
 Assistant Professor

Latest degree
 Ph.D.

Other areas of specialty/work
 Health Promotion

Street address
 Shiraz - Zand Avenue opposite Palestine Street -
 Central building

City
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 Fars

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 7134814336

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 +98 71 3235 9317

Email
 Trakhshani@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
 Shiraz University of Medical Sciences

Full name of responsible person
 Azita

Position
 Student

Latest degree
 Bachelor

Other areas of specialty/work
 Midwifery

Street address

Andimeshk

City

Andimeshk

Province

Khouzestan

Postal code

111111111

Phone

009015892517

Email

rahmati_a@ajums.ac.ir

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

Dissatisfaction participants

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

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

Does not apply

When the data will become available and for how long

Does not apply

To whom data/document is available

Does not apply

Under which criteria data/document could be used

Does not apply

From where data/document is obtainable

Does not apply

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

Does not apply

Comments