

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Examining educational effect based on health belief model on the improving of the oral health treatments of patients with type 2 diabetes.

Protocol summary

Summary

This study is an intervention with the aim of educational effects specification based on oral health behaviors in patients with type 2 diabetes. The study population; are patients with diabetes type2 under cover of diabetes clinic of Kashan's Matini Hospital. The sample content is of 120 people. The samples were selected randomly (draw) in the intervention and control groups (Each group;60 individual). Inclusion criteria: patients who are covered by clinic; 40 to 60 years old and literate; without artificial teeth and oral disease; without recent radiotherapy and dialysis; using dry mouth drugs is avoided. Exclusion Criteria: Patient's unwillingness to continue the participation in the study; absence of more than 2 session. This study was designed based on the health belief model and it'll be done by this process: Samples were selected and divided into two groups of control and intervention; Pre-test questionnaire; Educational intervention in4 sessions or more according to the needs; 60 minutes of intervention group about the anatomy of mouth and teeth; the impact of diabetes on oral health; signs and symptoms of oral disease; brushing and flossing correctly and gum massages; the impact of diet and exercise on diabetes treatment based on health belief model for intervention in a month; only the control group will receive the routine clinic training; perform post-test questionnaire 3 months after the intervention; analyzing and comparing information. The main variable outcome is the performance of diabetic patient.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050733847N1**

Registration date: **2017-06-14, 1396/03/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

Name

Maryam MalekMahmoodi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5543 0515

Email address

m.malekmahmoudi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Supplied by Vice President Of Research; Arak University of Medical Science

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-08-06, 1396/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining educational effect based on health belief model on the improving of the oral health treatments of patients with type 2 diabetes.

Public title

Effect of education based on health belief model on the improving of the oral health

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: it will be contacted with literate patients who have the record in diabetes clinic in order to study on their patient file. Moreover; in case of satisfaction and being interested in the subject; they will be able to register for studying. Being literate; living in Kashan; aged 40 to 60 years Owning the file at station; not having oral disease including gingivitis; infections of the oral cavity or tooth damage; lack of history of radiation therapy. (During radiotherapy (radiation) In case the entered radiation to neck and head influences the salivary glands; it will lead to disorder in salivating). In addition the patients who receive hemodialysis; they will be faced with dry mouth (Xerostomia) by virtue of limitation in consuming liquids amount or taking drugs with side effects of dry mouth (such as antidepressants; antihistamines and decongestants; antidiarrheal medications; muscle relaxant; drugs for high blood pressure; urinary inconvenience; the ones for Parkinson disease; AIDS and diabetes can cause dry mouth in individuals.No artificial teeth; not being under medical supervision and patients with lack of advanced dental disease based on information contained in the file. Exclusion Criteria: patient's unwillingness to continue the participation in the study; absence of more than 2sessions.

Age

From **40 years** old to **60 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

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

Arak University of Medical Sciences

Street address

Basij square;Pardis Educational Complex Department of Education and Research; Arak

City

Arak

Postal code

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.ARAKMU.REC.1395.444

Health conditions studied

1

Description of health condition studied

Oral Dieaseas

ICD-10 code

k05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Oral health behavior's promotion

Timepoint

Before and three month after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

The structural health belief model score(allergy ;intensity; benefits and barriers; cues to action and efficacy.

Timepoint

Before and three months after intervention

Method of measurement

Questionnaire

2

Description

Secondary outcomes 2 :performance score of the oral health behavior's promotion

Timepoint

Before and three months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention2: only the control group will receive the

routine diabetes clinic training.

Category

Behavior

2

Description

Intervention 1: Education based on health belief model in intervention group for 4 educational sessions according to the needs; 1 hour via lecture and discussion using training manual and etc. with data collection through questionnaire or interview before and 3 months after the intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Kashan's Matini Hospital

Full name of responsible person

Malekmahmoodi Maryam

Street address

Amir kabire street; Matini hospital; Kashan

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research; Arak University of Medical Science.

Full name of responsible person

Dr. Ali Anoshirvani; Vice President of Research

Street address

Basij square ; Campus Educational Complex; Deputy Education and Research

City

Arak

Grant name

1711

Grant code / Reference number

1711

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

Yes

Title of funding source

Vice President of Research; Arak University of Medical Science.

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

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohsen Shamsi

Position

Phd in Education and Health Promotion; Faculty of Arak University of Medical Science.

Other areas of specialty/work

Street address

Mustafa Khomein Street; School of Health; Arak

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 6443

Fax

Email

mohsen_shamsi1360@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Mohsen Shamsi

Position

PHD Associate Professor

Other areas of specialty/work

Street address

Mustafa Khomeini Street; School of Health; Arak

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 6443

Fax

Email

mohsen_shamsi1360@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Maryam Malekmahmoodi

Position

Master of Science Student.

Other areas of specialty/work**Street address**

Mustafa Khomeini Street; school of Health ; Arak

City

Arak

Postal code

38181-4-6851

Phone

+98 86 3368 6443

Fax**Email**

malekmahmoodi.ma@gmail.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