

# 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

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##### 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**

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**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*