

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Aug 2026

### The effect of educational intervention based on Adult Learning Theory on oral health related quality of life among the elderly referred to dental clinic of Ahvaz Jundishapur University of Medical Sciences

#### Protocol summary

##### Study aim

The present study was conducted to determine the impact of educational intervention based on Adult Learning Theory on oral health related quality of life of the elderly.

##### Design

Clinical trials with intervention and control group (with parallel groups), blind and randomized using 6 blocks.

##### Settings and conduct

The place of study was all parts of dental faculty of Ahvaz Jundishapur University of Medical Sciences. Participants were randomly divided into experimental and control groups. After pre-test, educational programs were conducted for the interventional group. After one month, the questionnaire was again administered in both groups. Then, the results of pre-test and post-test were compared in each group separately.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria for this study were fluency in Persian, informed consent to participate in the study, good psychological and mental status, minimum score of the short cognitive performance test (>6) and literacy. Age less than 60 years old and having psychological disorders were non-admission conditions.

##### Intervention groups

Intervention group: The intervention included an individual training method using motivational interviewing, an e-learning method in the form of sending three short messages once a week and a group discussion method that was held in 1 one-hour session. Control group: control group received routine cares of dental clinic of Ahvaz Jundishapur University of Medical Sciences.

##### Main outcome variables

The overall score of oral health related quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120910010804N13**

Registration date: **2018-12-16, 1397/09/25**

Registration timing: **retrospective**

Last update: **2018-12-16, 1397/09/25**

Update count: **0**

##### Registration date

2018-12-16, 1397/09/25

##### Registrant information

##### Name

Marzieh Araban

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

تهران

##### Email address

m.araban@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-01, 1396/03/11

##### Expected recruitment end date

2017-07-21, 1396/04/30

##### Actual recruitment start date

2017-06-01, 1396/03/11

##### Actual recruitment end date

2017-07-21, 1396/04/30

##### Trial completion date

2017-11-30, 1396/09/09

### Scientific title

The effect of educational intervention based on Adult Learning Theory on oral health related quality of life among the elderly referred to dental clinic of Ahvaz Jundishapur University of Medical Sciences

### Public title

The effect of education on oral health related quality of life

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Being fluent in persian Informed consent to participate in the study Good psychological and mental status according to the clinician's diagnosis Minimum score of the short cognitive performance test (>6) Having at least ability to read and write

#### Exclusion criteria:

Receiving private sectors care

### Age

From **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: **92**

Actual sample size reached: **86**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Allocating subjects to the study groups (intervention and control) was done random block using six blocks. This was done with WinPepi11.0 software (<http://www.brixtonhealth.com/pepi4windows.html>). This software generates random groups. In each block, 3 subjects were from the control group and 3 subjects were from the intervention group, which was arranged randomly. Finally, 16 blocks were used. The steps of using the software listed were as follows: ETCETERA, Randomization (Random allocation) , Balanced Randomization, Successive blocks.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In order to reduce the probability of information bias, the person evaluating the results (post-test) of the educational group was blinded to the participants' group assignment.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Ahvaz Jundishapur University of Medical Sciences, Esfand street, Golestan

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

61357-15794

#### Approval date

2017-06-17, 1396/03/27

#### Ethics committee reference number

IR.AJUMS.REC.1396.315

## Health conditions studied

### 1

#### Description of health condition studied

Oral health related Quality of life in the elderly

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Oral health related quality of life in the elderly

#### Timepoint

Before the intervention and one month after the intervention is completed

#### Method of measurement

Standard questionnaire of Geriatric Oral Health Assessment Index

## Secondary outcomes

### 1

#### Description

The Score of Effectiveness of Adult Learning Theory

#### Timepoint

Before the intervention and one month after the intervention

#### Method of measurement

Questionnaire consisted of 8 researcher-made questions

## Intervention groups

### 1

#### Description

Intervention group: using face-to-face training methods in the form of 15 minute individual training using motivational interviewing methods, e-learning method (sending educational SMS) which included three short messages that were sent once a week for Individuals and the group discussion method was used as a 1-hour session.

#### Category

Lifestyle

### 2

#### Description

Control group: control group received routine cares of dental clinics of Ahvaz Jundishapur University of Medical Sciences.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry of Ahvaz University of Medical Sciences

##### Full name of responsible person

Elham Shokouhi

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Ahvaz University of Medical Sciences, Esfand street, Golestan

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+98 61 3333 3477

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e\_shokouhi71@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr.Mohamad Badavi

##### Street address

Deputy of Research and Technology of Ahvaz University of Medical Sciences, Esfand street, Golestan

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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

Ahvaz 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

Ahvaz University of Medical Sciences

##### Full name of responsible person

Dr.Marzieh Araban

##### Position

Assistant Professor of Ahvaz University of Medical Sciences

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Health Promotion

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Ahvaz University of Medical Sciences, School of Public Health, Department of Health Education and Promotion

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Person responsible for updating data**

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**Full name of responsible person**

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**Position**

Assistant Professor Ahvaz University of Medical Sciences

**Latest degree**

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**Other areas of specialty/work**

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**Email**

araban62@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data studied is sharing after unobtrusive.

**When the data will become available and for how long**

The access to information after publishing the results

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

The terms of sending the document will be explained to the requesting person.

**From where data/document is obtainable**

araban62@gmail.com e\_shokouhi71@yahoo.com

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

The request will be answered by the research team after the review.

**Comments**