

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Designing, implementing and evaluation an educational program to improve the oral and dental health of the elderly in Hamadan city in 2023

Protocol summary

Study aim

Designing, implementing and evaluating an educational program to improve the oral and dental health of the elderly in Hamadan city in 2023

Design

A clinical trial with a control group, multi-stage cluster sampling, without blinding and randomized on 577 elderly people.

Settings and conduct

After obtaining the necessary permits, first the list of comprehensive health centers in Hamedan will be received, then three comprehensive health centers in each of the four regions of Hamedan will be randomly selected for study. In the next step, the sample size will be determined according to the number of comprehensive health centers in each of the 4 regions of Hamedan city and the population of elderly people over 60 covered by each center in that region. Then, by visiting each center in person, the elderly are included in the study according to the sample size and based on the entry and exit criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: at least 65 years old and having informed consent Exclusion criteria: patients with complete edentulism

Intervention groups

Intervention group: use of educational program Control group: using routine training

Main outcome variables

Behavior: Self-care behaviors in the field of oral health. Community Periodontal Index: Evaluation of periodontal condition based on presence of calculus, gingival bleeding and presence of periodontal pocket. Simplified Oral Hygiene Index: Evaluation of dental debris and calculus based on the involved surfaces of index teeth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230428058016N1**
Registration date: **2023-06-05, 1402/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-05, 1402/03/15**

Update count: **0**

Registration date

2023-06-05, 1402/03/15

Registrant information

Name

Mahboubeh Babaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3252 0182

Email address

m.babae74@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Designing, implementing and evaluation an educational program to improve the oral and dental health of the elderly in Hamadan city in 2023

Public title

Effect of educational program on improving the oral and dental health of the elderly

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Minimum age of 65 years Having informed consent

Exclusion criteria:

Patients with complete edentulism

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **577**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study is a multi-stage cluster. Sampling will be done using a random number table. For this purpose, a list of all comprehensive health centers will be received first, and a two-digit code will be given to each comprehensive health center (codes 01 to 35 for comprehensive health centers). To choose a comprehensive health center, refer to the table of random numbers and select the starting point. The starting point will be done by closing the eyes and placing a finger or the tip of the pen on the table. Then it will move in the direction of the line based on the adjacent two-digit numbers. In this path, two types of numbers are encountered, one of which is smaller than the total number of comprehensive health centers and the other type is larger than the number of comprehensive health centers. Only smaller numbers will be selected for sampling. The selected number is actually the central code that is selected as a sample. Then, the elderly of each center will be included in the study based on having the entry and exit criteria.

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 Hamadan University of medical sciences

Street address

Hamadan University of medical science, Shahid Fahmide Boulevards

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.UMSHA.REC.1402.109

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

Oral health

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Percentage of people who brushed twice a day with a toothpaste containing fluoride

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Behavior standard questionnaire

2**Description**

Use dental floss at least once a day

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Behavior standard questionnaire

3**Description**

Mouthwash use

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Behavior standard questionnaire

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

Determining the rate of periodontal tissue health of each person

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Clinical examination by a dentist

2

Description

Determining the rate of dental debris and calculus in each person

Timepoint

At the beginning of the study and 12 weeks later

Method of measurement

Clinical examination by a dentist

Intervention groups

1

Description

Intervention group: Intervention group: The second intervention group: The training program in this group will include 6 face-to-face training sessions for the elderly during four months. Also, a brochure will be prepared for geriatric nurses, which will provide tips on the importance of oral and dental hygiene and its role in public health, and the goals and implementation of the intervention program. Interventions in the elderly are carried out with the help of support groups. The elderly will be trained in the following areas: the importance of oral and dental hygiene, knowledge of tooth and periodontal structure, awareness of oral and dental diseases (decay and periodontal diseases) and their causes, ways to prevent oral and dental diseases .

Category

Prevention

2

Description

Control group: Receive routine programs and training

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Dibaj comprehensive health service center

Full name of responsible person

Mohsen Nowruzi

Street address

Kamal Abad area, Mirzadeh Eshghi Street

City

Hamadan

Province

Hamadan

Postal code

6516764741

Phone

+98 81 3833 1024

Email

m.babae74@gmail.com

2

Recruitment center

Name of recruitment center

Samii Modares comprehensive health service center

Full name of responsible person

Mohammad Hossein Azimian

Street address

Next to the police station, Modares town

City

Hamadan

Province

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Postal code

6517833193

Phone

+98 81 3829 0100

Email

m.babae74@gmail.com

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Recruitment center

Name of recruitment center

Sami Ostadan comprehensive health service center

Full name of responsible person

Fatemeh Hesami

Street address

Hakim Street, Murad Bey valley old road, Ostadan town

City

Hamadan

Province

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Postal code

6518777181

Phone

+98 81 3824 3300

Email

m.babae74@gmail.com

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Recruitment center

Name of recruitment center

Imam Khomeini Comprehensive Health Service Center

Full name of responsible person

Susan Mahtabani

Street address

In front of Ghadir complex, Jihad street, Beheshti town

City

Hamadan

Province

Hamadan

Postal code

6515794755

Phone

+98 81 3262 3367

Email

m.babaee74@gmail.com

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Recruitment center

Name of recruitment center

Shohada comprehensive health service center

Full name of responsible person

Fariba Asadi

Street address

Takhti street, Imam Khomeini Square

City

Hamadan

Province

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Postal code

6515617314

Phone

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Email

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Recruitment center

Name of recruitment center

Imam Sajjad Comprehensive Health Service Center

Full name of responsible person

Zahra Ranjbaran

Street address

Behind the oil depot, Shahid Chitsazian Blvd

City

Hamadan

Province

Hamadan

Postal code

6514764675

Phone

+98 81 3265 3018

Email

m.babaee74@gmail.com

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Recruitment center

Name of recruitment center

Shahid Karbasian Comprehensive Health Service Center (PA)

Full name of responsible person

Maryam Mansour

Street address

Shahid Yarntaghlo Alley, At the end of Khizr

City

Hamadan

Province

Hamadan

Postal code

6519654571

Phone

+98 81 3275 5199

Email

m.babaee74@gmail.com

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Recruitment center

Name of recruitment center

Banoushreifi Comprehensive Health Service Center

Full name of responsible person

Mehdi Amini

Street address

Next to Hijrat High School, Ayatollah Talahi Blvd

City

Hamadan

Province

Hamadan

Postal code

6513663131

Phone

+98 81 3265 1823

Email

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Recruitment center

Name of recruitment center

Samii comprehensive health service center in Madani town

Full name of responsible person

Mojtaba Badri

Street address

Block 7,Phase 2, Shahrak Madani

City

Hamadan

Province

Hamadan

Postal code

6513993436

Phone

+98 81 3429 2323

Email

m.babaee74@gmail.com

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Recruitment center

Name of recruitment center

Farhangian comprehensive health service center

Full name of responsible person

Maryam Lakzadeh

Street address

Student Street, Moalem Square, Phase1, Farhangian town

City

Hamadan

Province

Hamadan

Postal code

6519963449

Phone

+98 81 3254 9033

Email

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Recruitment center

Name of recruitment center

Imam Hossein Comprehensive Health Service Center

Full name of responsible person

Mehdi Heydari Karamat

Street address

Friday Alley, Vahdat Blvd, Khizr

City

Hamadan

Province

Hamadan

Postal code

6513719196

Phone

+98 81 3266 0550

Email

m.babae74@gmail.com

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Recruitment center

Name of recruitment center

Khatam comprehensive health service center

Full name of responsible person

Zohreh Atri

Street address

Tawheed Street

City

Hamadan

Province

Hamadan

Postal code

6518718886

Phone

+98 81 3422 8028

Email

m.babae74@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

4th floor, Headquarters of Hamadan University of medical science, Shahid Fahmideh Boulevards

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۷۸

Phone

+98 81 3131 4058

Email

Fanavari@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mahboubeh Babaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Hamadan university of medical sciences, Fahmideh St

City

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Hamadan

Postal code

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Phone

+98 81 3252 0182

Fax**Email**

m.babae74@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mahboubeh Babaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mahboubeh Babaei
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
Street address
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City
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Fax
Email
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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 is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

People who intend to use the study data for review articles and meta-analysis

From where data/document is obtainable

Mahboubeh Babaei email

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

After checking the requester's email by Zeinab Mosayebi, if the conditions are met, the data will be sent to them 3 days later.

Comments