Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Oral health promotion interventions based on Health Action Process Approach model among elderly in Tehran in 2021

Protocol summary

Study aim
Determining the effect of oral health promotion interventions based on the Health Action Process Approach model (HAPA)in Tehran elderly in 2021

Design
Cluster randomized controlled trial with parallel groups, double-blind, target population of the elderly aged 60 years and older living in Tehran, two intervention groups(each group of 150)

Settings and conduct
Samples are collected from the houses of active neighborhoods under the municipalities of 22 districts of Tehran by random multi-stage cluster sampling. The clusters are 24 houses of Tehran Municipality neighborhood in three geographical regions of north, south and center that are randomly selected. In each cluster, 15 elderly people who are randomly selected to participate in the study are invited to participate in the study.. Data collection: by completing the information form and Geriatric Oral Health Assessment Index and Health Action Process Approach questionnaire: oral examinations Follow-ups: one to three months after the intervention The examiner will be different in the baseline and follow up stages. Examiners in the baseline and follow-up stages are unaware of the study groups and how they are allocated (Double blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 60 years and older; Ability to communicate with researchers; sign the informed consent form Exclusion criteria: Debilitating disease; Uncontrolled systemic disease; Non-Iranian citizens

Intervention groups
Group A: Practical training in oral health by a dentist with an educational pamphlet (both containing Health Action Process Approach model structures) Group B (control group): Practical oral health training by the head of the neighborhood health center with an educational pamphlet (both containing Health Action Process Approach model structures)

Main outcome variables
Oral Hygiene Index; Oral health behaviors

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200928048868N1**
Registration date: **2020-12-07, 1399/09/17**
Registration timing: **prospective**

Last update: **2020-12-07, 1399/09/17**
Update count: **0**

Registration date
2020-12-07, 1399/09/17

Registrant information

Name
Fatemeh Moghaddam Ghaeini

Name of organization / entity

Country
Iran (Islamic Republic of)

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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-04, 1399/10/15

Expected recruitment end date
2021-05-20, 1400/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Oral health promotion interventions based on Health Action Process Approach model among elderly in Tehran in 2021

Public title
Oral health promotion based on behavioral model among elderly

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
60 or more than 60 years old Ability to communicate with researchers sign the informed consent and voluntary participation in the research

Exclusion criteria:
Debilitating disease Uncontrolled systemic disease Non-Iranian citizens

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
To sample this study, a controlled clinical trial is performed by randomized multistage cluster sampling. According to the geographical map of Tehran, it is divided into three regions: north, center, and south. Tehran has 22 municipal districts, of which the north of Tehran includes 6 districts (1, 2, 3, 4, 5, and 22), the center of Tehran includes 10 districts (6, 7, 8, 9, 10, 11, 12, 13, 14 and 21) and the south of Tehran includes 6 districts (15, 16, 17, 18, 19 and 20). Using the index and rand functions of Excel software, two regions and a total of 6 municipal regions are selected randomly from each of these three regions of north, south, and center (stratified randomization). The city of Tehran includes 354 active neighborhood houses, each of the 22 districts of Tehran includes a number of these neighborhood houses. After randomly selecting 6 regions, the number of subdirectories of each of these regions is determined separately and entered into Excel software. From among the neighborhoods of each region, 4 houses are randomly selected with Excel software. Eventually, we will have 24 neighborhood halls (clusters). From the 4 houses selected in each area, 2 houses by simple randomization are assigned to intervention A and 2 houses to intervention B (control). According to the sample size of 300 people in this study, about 15 elderly people from each of the 24 selected clusters (24 neighborhood halls) will participate. To select people in each neighborhood home, we act in such a way that we prepare a list of elderly people who are members of the neighborhood home and using Excel software, 15 people are randomly selected from them and they are contacted and asked for Participation in the study is invited. If several people do not attend the study, we randomly select alternative people from the same list

Blinding (investigator's opinion)
Double blinded

Blinding description
1. The examiner will be different in the baseline and follow up stages. Calibration of the examiners (inter-examiner) and each examiner will be done with himself (intra-examiner). 2. Examiners in the baseline and follow up stage are unaware of the study groups and how to allocate. 3. The people who do the training in group A (dentist) and group B (in charge of the neighborhood health center) will be different and are not study researchers. These people are trained to intervene. 4. When entering SPSS, the data will be entered with special codes so that the analyzer is not informed about the clusters and groups. 5. The researcher conducting the analysis is unaware of the intervention and allocation groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethnics committee School of Dentistry_Tehran university of medical sciences

Street address
Department of Community Oral Health, School of Dentistry, Tehran University of Medical Sciences (TUMS), North Karegar Ave.

City
Tehran

Province
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1439955991

Approval date
2020-09-27, 1399/07/06

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1399.102

Health conditions studied

1

Description of health condition studied
oral health promotion in elderly
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Oral Health behaviors
Timepoint
At the beginning of study, one and three month after intervention
Method of measurement
Health Action Process Approach questionnaire and World Health Organization (WHO) standard form in elderly oral health habits

2

Description
Oral Hygiene index
Timepoint
At the beginning of study: one and three month after intervention
Method of measurement
Oral and dental examination form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Practical training of oral health based on Health Action Process Approach model structures by a dentist along with presentation of educational pamphlet containing model structures
Category
Prevention

2

Description
Control group: Practical oral health training based on Health Action Process Approach model structures by the head of the neighborhood health center with the presentation of an educational pamphlet containing model structures
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Municipality district No.1
Full name of responsible person
Zeynab Nasiri
Street address
Shahid Bahonar Ave.,Ghods square
City
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Tehran
Postal code
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Fax
+98 21 2271 4095
Email
salamat-ejtemaei@tehran.ir

2

Recruitment center
Name of recruitment center
Municipality district No. 22
Full name of responsible person
Zeynab Nasiri
Street address
North of Shahid Bgheri Shahrak, West Hemmat Highway
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Tehran
Province
Tehran
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1494617542
Phone
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3

Recruitment center
Name of recruitment center
Municipality district No. 7
Full name of responsible person
Zeynab Nasiri
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No. 1 building, Shahid Ghandi Ave.
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4

Recruitment center

Name of recruitment center
Municipality district No.11
Full name of responsible person
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Ghazvin Ave., Ghazvin square
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Phone
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5

Recruitment center

Name of recruitment center
Municipality district No.15
Full name of responsible person
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6

Recruitment center

Name of recruitment center
Municipality district No. 19
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Moghaddam Ghaeini
Position
PhD student of Community Oral Health
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available