Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

Evaluation of the effect of educational interventions on preventive behaviors of oral cancer based on the Theory of Planned Behavior among people aged 15 years and more: A cluster randomized controlled trial

Protocol summary

Study aim

Evaluation of the effect of educational interventions on preventive behaviors of oral cancer based on the Theory of Planned Behavior

Design

Cluster randomized controlled trial, with parallel groups, single blind, people aged 15 years and more living in Tehran, two intervention groups, simple randomization using Excel software, 400 people, participated in study in 2022

Settings and conduct

The health centers in two low-advantaged and very low-advantaged areas of Tehran located in five districts covered by Tehran University of Medical Sciences, which have the necessary criteria for better implementation of study will be selected, and from these centers, 20 centers will be randomly selected, and in each center, 20 people will be selected by simple random sampling. Data will be collected using structured interviewer-administered questionnaire of Theory of Planned Behavior, which will be again completed one and three months after the intervention. The data will be entered into STATA software with special codes, so that the analyzer is not informed about the clusters and groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 15 years and more; Living in low-advantaged or very low-advantaged area of Tehran; Absence of physical and mental disabling diseases; Agreement to sign the informed consent form Exclusion criteria: Non-Iranian citizens; Unwillingness to participate in face-to-face educational sessions; Unwillingness to work with virtual social networks; Inability to use smartphone applications

Intervention groups

Intervention group 1 (control group): Education on oral cancer prevention using lecture presentation and pamphlet based on the Theory of Planned Behavior,

Intervention group 2: Education on oral cancer prevention using smartphone based on the Theory of Planned Behavior

Main outcome variables

Preventive behaviors of oral cancer; Knowledge about oral cancer

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220221054086N1**
Registration date: **2022-03-04, 1400/12/13**
Registration timing: **prospective**

Last update: **2022-03-04, 1400/12/13**
Update count: **0**

Registration date

2022-03-04, 1400/12/13

Registrant information

Name

Anoosheh Ghasemian

Name of organization / entity

Country

Iran (Islamic Republic of)

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a-ghasemian@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of educational interventions on preventive behaviors of oral cancer based on the Theory of Planned Behavior among people aged 15 years and more: A cluster randomized controlled trial

Public title

Evaluation of the effect of educational interventions on prevention of oral cancer based on the behavior change model

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 15 years and more Living in low-advantaged or very low-advantaged area of Tehran Absence of physical and mental disabling diseases Minimum literacy of reading and writing Having a smartphone and installed applications Willingness to participate in the study and agreement to sign the informed consent form

Exclusion criteria:

Non-Iranian citizens Unwillingness to participate in face-to-face educational sessions Unwillingness to work with virtual social networks Inability to use smartphone applications

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be performed using simple cluster random sampling. Based on the socio-economic development index, the city of Tehran is divided into five areas of advantaged, relatively-advantaged, semi-advantaged, low-advantaged, and very low-advantaged. The city of Tehran has 22 districts, of which the advantaged area includes four districts (1, 2, 3, 6), the relatively-advantaged area includes two districts (5, 7), the semi-advantaged area includes six districts (4, 8, 11, 13, 21, 22), the low-advantaged area includes five districts (9, 10, 12, 14, 20), and the very low-advantaged area includes five districts (15, 16, 17, 18, 19). Two areas of low- and very low-advantaged will be selected according to the research goal. Then, the list of health centers in these two areas will be extracted based on their locations in the districts covered by Tehran University of Medical Sciences, including districts 10, 15, 16, 17, and 19, which include 100 centers. Next, among the health centers located in these districts, the centers which have capability to implement study better will be selected based on the criteria such as activeness of the center, cooperation of the center, sufficient number of clients, amount of participation of covered people, and facilities of the center including appropriate space and place for education. The list of selected health centers that are considered as clusters will be prepared, and from these selected centers, 20 centers will be randomly selected, of which 10 centers will be allocated to intervention group 1 (control) and 10 centers to intervention group 2 by simple randomization using Excel software. Then, according to the sample size of 400 people, in each of the 20 health centers, 20 people will be selected, in such a way that the list of people covered by these centers will be prepared, and 20 of them will be selected by simple random sampling and invited to participate in the study, and if people do not have willing to participate in the study, alternative people from the prepared list will be also selected by simple random sampling.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data will be entered into STATA software with special codes, so that the analyzer is not informed about the clusters and groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Dentistry, Tehran University of Medical Sciences

Street address

Department of Community Oral Health, School of Dentistry, Tehran University of Medical Sciences, North Kargar Ave

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1400.189

Health conditions studied

1

Description of health condition studied
Prevention of oral cancer
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Preventive behaviors of oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

2

Description
Knowledge about oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

Secondary outcomes

1

Description
Behavioral intention about preventive behaviors of oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

2

Description
Attitude toward preventive behaviors of oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

3

Description
Subjective norm about preventive behaviors of oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

4

Description
Perceived behavioral control about preventive behaviors of oral cancer
Timepoint
At the beginning of study, one and three months after intervention
Method of measurement
Structured interviewer-administered questionnaire of Theory of Planned Behavior

Intervention groups

1

Description
Control group: Education on oral cancer prevention by educated health volunteers using two sessions of 10-15 minutes lecture presentation in form of PowerPoint slides, and presentation of pamphlet based on the structures of the Theory of Planned Behavior, with interactive group discussions, and questions and answers to questions
Category
Prevention

2

Description
Intervention group: Education on oral cancer prevention by educated health volunteers using information presentation on smartphone in form of educational and motivational messages, pictures, and videos in WhatsApp groups based on the structures of the Theory of Planned Behavior, with interactive group discussions, and questions and answers to questions
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
District 10, South Tehran Health Center
Full name of responsible person
Mohammad Reza Salmani
Street address
Shafiei Alley, Vesal Shirazi St, Keshavarz Blvd
City
Tehran
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Tehran
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1311754339
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Email
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2

Recruitment center
Name of recruitment center
District 15, South Tehran Health Center
Full name of responsible person
Mohammad Reza Salmani
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Shafiei Alley, Vesal Shirazi St, Keshavarz Blvd
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3

Recruitment center
Name of recruitment center
District 16, South Tehran Health Center
Full name of responsible person
Mohammad Reza Salmani
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4

Recruitment center
Name of recruitment center
District 17, South Tehran Health Center
Full name of responsible person
Mohammad Reza Salmani
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5

Recruitment center
Name of recruitment center
District 19, South Tehran Health Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi
Street address
6th floor, Vice Chancellor for Research and Technology, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd
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Postal code
1417653761
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Email
vcr@tums.ac.ir
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

Anoosheh Ghasemian

Position

PhD student of Community Oral Health

Latest degree

Medical doctor

Other areas of specialty/work

Community Oral Health

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Associate Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

PhD student of Community Oral Health

Latest degree

Medical doctor

Other areas of specialty/work

Community Oral Health

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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