

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Feb 2023

### 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)

##### Phone

+98 21 8801 5950

##### Email address

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

##### Province

Tehran  
**Postal code**  
1311754339  
**Phone**  
+98 21 6695 0069  
**Email**  
Behdasht-Jonoob-Tehran@sina.tums.ac.ir

## 2

**Recruitment center**  
**Name of recruitment center**  
District 15, South Tehran Health Center  
**Full name of responsible person**  
Mohammad Reza Salmani  
**Street address**  
Shafiei Alley, Vesal Shirazi St, Keshavarz Blvd  
**City**  
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**Province**  
Tehran  
**Postal code**  
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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  
**Street address**  
Shafiei Alley, Vesal Shirazi St, Keshavarz Blvd  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1311754339  
**Phone**  
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**Email**  
Behdasht-Jonoob-Tehran@sina.tums.ac.ir

## 4

**Recruitment center**  
**Name of recruitment center**  
District 17, South Tehran Health Center  
**Full name of responsible person**  
Mohammad Reza Salmani  
**Street address**  
Shafiei Alley, Vesal Shirazi St, Keshavarz Blvd  
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1311754339

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**Email**  
Behdasht-Jonoob-Tehran@sina.tums.ac.ir

## 5

**Recruitment center**  
**Name of recruitment center**  
District 19, South Tehran Health Center  
**Full name of responsible person**  
Mohammad Reza Salmani  
**Street address**  
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**Province**  
Tehran  
**Postal code**  
1311754339  
**Phone**  
+98 21 6695 0069  
**Email**  
Behdasht-Jonoob-Tehran@sina.tums.ac.ir

## **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  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1417653761  
**Phone**  
+98 21 8163 3698  
**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

**Street address**

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

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**Person responsible for updating data**

**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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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Katayoun Sargeran

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Community Oral Health

**Street address**

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

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**Province**

Tehran

**Postal code**

**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