Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of effectiveness of two in-person and virtual educational interventions in improving the oral health literacy of the adults

Protocol summary

Study aim
Comparison of in-person and virtual educational interventions in improving the oral health literacy of the adults

Design
Randomized clinical trial, Non-inferiority design, Parallel groups, Balanced block randomization, 2 groups of virtual and in-person education, The sample size is equal to 136 participants.

Settings and conduct
Adult visitors to the clinic of school of dentistry of Tehran university of medical sciences are selected using Haphazard non-probability sampling. After controlling the exclusion and inclusion criteria, informed consent is obtained from eligible volunteers. Then they will be randomly allocated to two groups of virtual or in-person education . Before and after and 3 months after the intervention, Oral health literacy adult questionnaire (OHL-AQ) is obtained from the participants.Validity and reliability of OHL-AQ is approved in the previous studies. Items reviewed in this questionnaire are consistent with the educational content. Blinding is only applied for the researcher analyzing the data.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults, aged between 18 and 65 years, capable of reading and writing who give informed consent to participate and have access to an online messenger . Exclusion criteria: The individuals participating in a similar educational intervention or have physical or mental disability.

Intervention groups
In the In-person educational intervention group, the researcher explains oral health tips and give educational pamphlets to the visitors. In the virtual educational intervention group, a short educational video is sent in an accessible online messenger. The educational content of the two interventions are the same.

Main outcome variables
Difference between OHL-AQ scores before the intervention and after/3 months after the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220106053643N1**
Registration date: **2022-02-08, 1400/11/19**
Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**
Update count: **0**

Registration date
2022-02-08, 1400/11/19

Registrant information

Name
Negar Ebrahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

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ebrahiminegar0@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-10-12, 1401/07/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of effectiveness of two in-person and virtual educational interventions in improving the oral health literacy of the adults

Public title
Evaluation of two in-person and virtual educational interventions in improving the oral health literacy of the adults

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
The participants who are able to read and wright in persian . The individuals who are willing to participate in the study and give informed consent. Participants who are older than 18 years old and younger than 65 years old . Participants who have access to an online messenger(such as Whats App messenger).

Exclusion criteria:
The individuals who participate in a similar educational study at the same time. The participants who have physical or mental disability. The participants who are unwilling to participate in the study .

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **136**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible participants will be randomly allocated to two groups of virtual and in-person educational interventions using balanced block randomisation . Each block contains 10 cards inserted in 10 non-transparent envelopes(5 cards for virtual intervention and 5 cards for in-person intervention). After controlling inclusion and exclusion criteria , each eligible participant will choose one envelope from the respective block randomly .

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants and the researcher performing the intervention can't be blinded because their awareness of the type of intervention is inevitable. Only the researcher analyzing the data will be blinded.

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 of Tehran University of Medical Sciences

Street address
North Karegar St,Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1439955991

Approval date
2022-01-01, 1400/10/11

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1400.181

Health conditions studied

1

Description of health condition studied
oral health literacy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Oral health literacy score of OHL-AQ questionnaire

Timepoint
At the beginning of the study (before the intervention) , After the intervention , 3 months after the intervention

Method of measurement
Oral Health Literacy-Adult Questionnaire (OHL-AQ) : This questionnaire was used in previous studies to evaluate the oral health literacy of the adults in Tehran and its validity and reliability was approved. The OHL-AQ questionnaire consists of 14 questions and 17 items that are divided into 4 sections: text comprehension ability , simple computational skills, listening / communication skills and decision making. The maximum achievable score is 17. Each correct answer is equal to one score ; no scores is considered for the wrong answers . The questionnaire also asks the name, phone number, age, sex, and the level of education of the participants. It is worth mentioning that all the answers and information will be kept confidential. The questionnaires obtained after 3 months and after the virtual intervention will be sent in a messenger of the individual's choice. At the beginning of the questionnaire, participants are asked to answer the questions using their own knowledge and not

to seek help from others and not to refer to the educational content.

Secondary outcomes

empty

Intervention groups

1

Description
Virtual educational intervention group:Virtual education is in the form of a short video explaining the same content of face-to-face education and depicts related concepts and topics. The video is sent to the participants in an online messenger (such as WhatsApp or Telegram) of the person's choice. Standard video design criteria are followed.
Category
Other

2

Description
In-person educational intervention group: Face-to-face education is performed in the form of an interactive conversation with the individual , oral presentation of oral health tips and presentation of a pamphlet. In-person education takes place in the waiting rooms of the clinic of the School of Dentistry of Tehran University of Medical Sciences. If several people are involved in its implementation, calibration is performed. The standard criteria for designing educational pamphlets are observed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The clinic of School of dentistry of Tehran University of Medical Sciences
Full name of responsible person
Negar Ebrahimi
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North Karegar St,Tehran-Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran
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1449614535
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tumspr@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
Katayoun Sargeran
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Community Oral Health
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Person responsible for updating data

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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
Yes - There is 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

Title and more details about the data/document
Clinical study report : More details about the study process will be shared ; For instance, details about scheduling of face-to-face and virtual interventions, how they'll have been performed, the performer of the intervention and calibration (if several people perform the intervention), how to collect information, the participants who'll have left the trial and the information related to data analysis , Analyst and statistical tests, study results and its conclusions.

When the data will become available and for how long
Access to the information starts 6 months after the results are published.

To whom data/document is available
Information about clinical study report can be made available for the researchers of the academic and scientific institutions , upon request .

Under which criteria data/document could be used
Provided that another researcher wants to access the report of this trial to compare the results with a similar study or to conduct a similar study , he/she can receive it via an email to the researcher.

From where data/document is obtainable
Researchers can apply for information via the following emails: k-sargeran@tums.ac.ir ebrahiminegar0@gmail.com

What processes are involved for a request to access data/document
After receiving the email , correctness of the information of the researcher will be checked through contacting the relevant university . If necessary , a consent will be obtained from the researcher to avoid plagiarism and Making the information available to people outside the study(the consent can be sent through an email) , then the information will be available for the researcher .

Comments