

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of two educational interventions including brochure or film on the awareness and self-reported performance of pregnant women regarding oral and dental health

Protocol summary

Study aim

To compare the effect of two educational interventions on the awareness and self-reported performance of pregnant women regarding oral and dental health.

Design

semi-experimental clinical trial, two parallel intervention groups, 70 samples. Randomization will be performed for each center using SAS software version 9, and for randomization of individuals in each center into two groups, a 4-block permutation method will be used.

Settings and conduct

Setting: Private women's and maternity clinics in Islamshahr. Conduct: After random distribution between the two intervention groups, the first intervention will be received at the clinic. After that, both video content and brochures will be sent again to mothers every month through social networks. The awareness and self-reported performance of mothers in both groups will be assessed using an online questionnaire, once before the intervention, immediately after the intervention at the clinic, and three times at one-month, three-month, and six-month intervals after the intervention. Blinding: Single-blind, the data analyst will be unaware of the interventions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women who have access to one of the social networks (WhatsApp, Telegram, Eitaa, etc.). Exclusion criteria: Individuals who are in emergency situations or have unfavorable general conditions, or do not provide written informed consent.

Intervention groups

Group 1: Receiving educational intervention in the form of a text with images through a brochure. Group 2: Receiving educational intervention in the form of audio-visual content through a video.

Main outcome variables

Awareness of dental and oral health; self-reported dental

and oral health performance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160910029765N3**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **prospective**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

Registration date

2023-10-24, 1402/08/02

Registrant information

Name

Mohammad Reza Khami

Name of organization / entity

Tehran University of Medical Sciences, School of Dentistry

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 5960

Email address

mkhami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of two educational interventions including brochure or film on the awareness and self-reported performance of pregnant women regarding oral and dental health

Public title

Comparing the effect of educating pregnant women through brochure or film on oral and dental health

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women Having access to one of the social networks such as WhatsApp, Telegram, Eitaa, etc

Exclusion criteria:

Emergency or unfavorable general conditions Not providing informed written consent

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering each district of Islamshahr as a cluster, clusters are selected, and then within each cluster, a private women's and maternity clinic is selected using simple random sampling. To randomize individuals in each center, a 4-block permutation block randomization method is used.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data collection tool is a self-administered anonymous questionnaire and only the participants know the confidential code which he/she writes in the baseline and follow up questionnaire to enable assessment of individual changes. All the data will be remained anonymous and confidential to the statistical analyst.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

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

City

Tehran

Province

Tehran

Postal code**Approval date**

2023-07-18, 1402/04/27

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1402.040

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

Awareness and self-reported performance of pregnant women regarding oral and dental health

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

Awareness of oral and dental health

Timepoint

Before the intervention, immediately after the intervention, 1, 3, and 6 months after the intervention

Method of measurement

Baseline questionnaire and follow-up questionnaire

2**Description**

Self-reported oral and dental health practice

Timepoint

Before the intervention, immediately after the intervention, 1, 3, and 6 months after the intervention

Method of measurement

Baseline questionnaire and follow-up questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: receiving educational intervention in the form of a text with images through a brochure

Category

Other

2

Description

Intervention group 2: receiving educational intervention in the form of audio-visual content through a video

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private women's and maternity clinics in Islamshahr

Full name of responsible person

Mohammad Reza Khami

Street address

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

City

Tehran

Province

Tehran

Postal code

1439955934

Phone

+98 21 8801 5960

Fax

+98 21 8801 5961

Email

mkhami@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

Keshavarz Blvd. Qods St. TUMS Headquarter, 6th floor

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

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

Mohammad Reza Khami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

Street address

End of North Kargar, School of Dentistry, Tehran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1439955934

Phone

+98 21 8801 5960

Fax

+98 21 8801 5961

Email

mkhami@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Khami

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry
Street address
End of North Kargar, School of Dentistry, Tehran
University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1439955934
Phone
+98 21 8801 5960
Fax
+98 21 8801 5961
Email
mkhami@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Khami
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Dentistry
Street address
End of North Kargar, School of Dentistry, Tehran
University of Medical Sciences
City

Tehran
Province
Tehran
Postal code
1439955934
Phone
+98 21 8801 5960
Fax
+98 21 8801 5961
Email
mkhami@tums.ac.ir

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