

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of Mobile-based Self-care Application for Oral-dental Hygiene of Pregnant Women on Dental plaque, Gingivitis and White spot lesions

Protocol summary

Study aim

Comparing the effectiveness of mobile-based self-care application for oral-dental hygiene of Pregnant Women on dental plaque, gingivitis and white spot lesions

Design

In this study, 70 pregnant women in two control groups and intervention at three time points, baseline, one month after using the application and three months after using it will be evaluated. The presenting dentist and the dentist evaluating the outcomes and pregnant women are blinded.

Settings and conduct

Dental plaque index, gingivitis and white spot lesions in 70 pregnant women in two control and intervention groups at three time points, baseline, one month after using the application and three months after using the application will be evaluated. In this study, the presenting dentist and the dentist evaluating the outcomes and pregnant women are blinded.

Participants/Inclusion and exclusion criteria

Inclusion - Age between 25 and 35 years - Willingness to participate in the study - Having a smart mobile phone - Ability to work with application program - Gestational age of the second and third trimesters of pregnancy (from the 15th week to the end of delivery) - Pregnant women without tooth decay and gum disease Exclusion - Having mental and physical disability - Having oral and dental diseases - Using drugs that affect the accumulation of dental plaque, such as antibiotics and antibacterial mouthwashes

Intervention groups

Control group: The dentist will present oral-dental hygiene principles to the control group. Also, this group will be given brochures prepared about oral and dental hygiene. Intervention group: people in the intervention group, in addition to receiving the oral-dental hygiene principles and brochures about oral-dental hygiene,

receive a mobile-based self-care application.

Main outcome variables

Dental plaque, Gingivitis index, White spot lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230624058570N1**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Sahar Khenarinezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8878 0736

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of Mobile-based Self-care Application for Oral-dental Hygiene of Pregnant Women on Dental plaque, Gingivitis and White spot lesions

Public title

Effectiveness of Mobile-based Application on Dental plaque, Gingivitis and White spot lesions in Pregnant Women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 25 and 35 years Willingness to participate in the study Having a smart phone Ability to work with applications Gestational age of the second and third trimesters of pregnancy (from the 15th week to the end of delivery) Pregnant women without tooth decay and gum disease

Exclusion criteria:

Having mental and physical disability Having oral and dental diseases Using drugs that affect the accumulation of dental plaque, such as antibiotics and antibacterial mouthwashes

AgeFrom **25 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample sizeTarget sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

The research sample will be 70 pregnant women referring to the oral and dental health unit of the health network covered by Mazandaran University of Medical Sciences. The people of the sample group will be divided into two control groups (35 people) and intervention (35 people) with the randomization tool of the sealed envelope. In this study, the dentist providing the common principles of oral and dental hygiene and the dentist evaluating the results will not know about the presence of each patient in the control and intervention groups. Also, pregnant women will be blinded to grouping.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the dentist providing the common principles of oral and dental hygiene and the dentist

evaluating the results will not know about the presence of each patient in the control and intervention groups. Also, pregnant women will be blinded to grouping. Therefore, the present study will be conducted as a double-blind randomized clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemat Highway, next to Milad Tower, Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2023-06-12, 1402/03/22

Ethics committee reference number

IR.IUMS.REC.1402.197

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

Oral-Dental Hygiene

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

Dental plaque index

Timepoint

At the beginning of the study (before the intervention), one month after using the application and three months after using the application

Method of measurement

Plaque disclosing tablet and Plaque ontrol record (O'Leary index)

2**Description**

Gingival Index (GI)
Timepoint
At the beginning of the study (before the intervention),
one month after using the application and three months
after using the application
Method of measurement
Loe and sillness index

3

Description
White spot lesions
Timepoint
At the beginning of the study (before the intervention),
one month after using the application and three months
after using the application
Method of measurement
Visual examination method

Secondary outcomes

empty

Intervention groups

1

Description
Control group: People in the control group will receive
the oral-dental hygiene principles orally by the dentist. In
addition, brochures prepared about oral-dental hygiene
will be given to the control group.
Category
Prevention

2

Description
Intervention group: Pregnant women in the intervention
group, in addition to receiving oral-dental hygiene
principles and oral-dental hygiene brochures, will also
receive a mobile-based self-care application.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Oral and dental hygiene unit of health network
covered by Mazandaran University of Medical
Sciences
Full name of responsible person
Farhad Gholami
Street address
Sari, Joibar Three Roads, the beginning of Vali Asr
Highway (Aj), Mazandaran University of Medical
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Farahnaz Sadoughi
Position
Professor of Health Information Management
Latest degree
Ph.D.

Other areas of specialty/work

Health Information Management

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Professor of Health Information Management

Latest degree

Ph.D.

Other areas of specialty/work

Health Information Management

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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

Latest degree

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Fax**Email**

khenarisahar73@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of a systematic review along with the oral-dental health application and the effect of the mobile application on dental plaque, gingivitis index and white spot lesions in pregnant women.

When the data will become available and for how long

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To whom data/document is available

Researchers interested in the subject of this study

Under which criteria data/document could be used

For use in selecting or designing a mobile -based self-care application on oral-dental hygiene for Pregnant Women

From where data/document is obtainable

sadoughi.f@gmail.com

What processes are involved for a request to access data/document

After receiving the data request email, the data will be sent to the researcher within 1 week.

Comments