Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The effect of SMS reminder after oral hygiene instruction on Plaque Index and oral health related quality of life(OHRQoL) in pregnant women: A randomized clinical trial

Protocol summary

Study aim

The effect of SMS reminder after oral hygiene instruction on Plaque Index and oral health related quality of life(OHRQoL) in pregnant women of Isfahan

Design

This study is an interventional randomized controlled clinical trial. The sampling method is simple and the samples of this study are from people referring to comprehensive health centers that have midwifery and dentistry (such as Mohkamkar health center in Zeinabia) They are elected in Isfahan in 1400. A total of 60 samples will be collected and divided into two groups of 30 intervention and control with a computer application.

Settings and conduct

Comprehensive health centers such asMohkam karl Health Center in Zeinabiyeh

Participants/Inclusion and exclusion criteria

Inclusion criteria included: willingness to participate in the project, the second or third month of pregnancy, not using drugs that affect periodontal conditions, including anticonvulsants (phenytoin), immunosuppressive drugs (cyclosporine) and calcium channel blockers (Nifedipine), the ability to accurately understand the questions of the questionnaire, the ability to read and access the mobile phone. Exclusion criteria include: the person's decision not to continue the plan, smoking, systemic diseases, use of orthodontic applause and the inability of the person to maintain oral health (due to oral injury or physical disability)

Intervention groups

Pregnant women who receive a reminder text message on a weekly basis after a health examination and oral health instruction.

Main outcome variables

Plaque index- Oral health related quality of life(ohip-14 index)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211109053015N1**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Adel Tabesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 2968

Email address

adel.tabesh@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of SMS reminder after oral hygiene instruction on Plaque Index and oral health related quality of life(OHRQoL) in pregnant women: A randomized clinical trial

Public title
The effect of SMS reminder after oral hygiene instruction on Plaque Index and oral health related quality of life(OHRQoL) in pregnant women: A randomized clinical trial

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women who visit health center with at least 18 years old Who are willing to attend In second or third month of pregnancy Being able to read Having access to cell phone

Exclusion criteria:

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
We assign a number to every participant from 1 to 60 and randomization happens using computer application.

Blinding (investigator's opinion)
Double blinded

Blinding description
The examiner examines the patients, however randomization happens by the researchist. The researchist is also uninformed about plaque index of patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
No. 44, Hosseini alley, Shariati street, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8173734761

Approval date
2021-11-01, 1400/08/10

Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.315

Health conditions studied

1

Description of health condition studied
Plaque index- Oral health related quality of life

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Plaque index- Oral health related quality of life

Timepoint
At the beginning of the study and 3 months after the start of sending reminder text messages

Method of measurement
Oral health impact profile questionnaire 14 (ohip-14) for oral health related quality of life and clinical examination by a calibrated person to evaluate plaque index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: People who receive a reminder SMS for 3 months a week on a specific day and time after a oral examination and health instruction.The general content of the messages will be about the importance of hygiene, especially during pregnancy, health recommendations and repetition of the points mentioned in the health education session.

Category
Lifestyle

2

Description
Control group: People who do not receive any reminder SMS after oral examination and health instruction.

Category

Lifestyle

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Zeinabieh comprehensive health care center

Full name of responsible person
Adel Tabesh

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No. 44, Hosseini alley, Shariati street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mansour Siavash

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Isfahan university of medical sciences

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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
Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Adel Tabesh

Position
Assistant proffessor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
Yes - There is 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
Can be published anonymously
When the data will become available and for how long
Post Analysis
To whom data/document is available
Public
Under which criteria data/document could be used
Request from University
From where data/document is obtainable
University
What processes are involved for a request to access data/document
letter to university
Comments