

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jul 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 Zeinabiah) 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 as Mohkam 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 appliance 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

Isfahan

## 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

## 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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##### Phone

+98 31 3627 2968

##### Email

adel.tabesh@dnt.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Mansour Siavash

##### Street address

Isfahan university of medical sciences

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673469

##### Phone

+98 31 3792 3120

##### Email

adel.tabesh@dnt.mui.ac.ir

##### 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

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Adel Tabesh

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assistant proffessor

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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**

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**