

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of oral health education program based on health belief model in improving oral health behaviors in pregnant women refferd to Jilard health center and Hazrate Fatemeh hospital in Damavand city in 1402-1403

Protocol summary

Study aim

Improving oral and dental health behaviors in pregnant women

Design

A clinical trial with a control group, with parallel groups on 200 randomized pregnant mothers using the rand function of Excel software based on the number of cases of mothers in two control and intervention groups.

Settings and conduct

Gillard Health Centers and Hazrat Fatemeh Hospital, Damavand city, based on the knowledge and attitudes of mothers towards oral and dental health

Participants/Inclusion and exclusion criteria

pregnancy

Intervention groups

Intervention group = oral health education during pregnancy and health assessment before and after education Evaluation control group = oral health evaluation

Main outcome variables

Knowledge and attitude-self-efficacy

General information

Reason for update

Acronym

HB M

IRCT registration information

IRCT registration number: **IRCT20240106060631N1**

Registration date: **2024-03-04, 1402/12/14**

Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

Name

Mojgan Faezi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2205 7611

Email address

drm.faezi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-06-04, 1403/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral health education program based on health belief model in improving oral health behaviors in pregnant women refferd to Jilard health center and Hazrate Fatemeh hospital in Damavand city in 1402-1403

Public title

The effect of oral health education program based on health belief model in improving oral health behaviors in pregnant women refferd to Jilard health center and

Hazrate Fatemeh hospital in Damavand city

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women referred in the first, second and third trimesters ability to read and write
Exclusion criteria:
Pregnant women referred in the first, second and third trimesters

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on the last file number - scores of the individual in the control group. even scores in the intervention group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق دانشگاه شاهد

Street address
hahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran

City
tehran

Province
Tehran

Postal code
3319118651

Approval date
2024-01-08, 1402/10/18

Ethics committee reference number
IR.SHAHED:REC.1402.100

Health conditions studied

1

Description of health condition studied

Decad tooth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of education on the knowledge and attitude of pregnant mothers on oral health

Timepoint

3 days a week from 9:00 a.m. to 1:00 p.m

Method of measurement

Knowledge and Attitude Questionnaire (Dr. Bahramian - Dr. Mohebi) - Self-Efficacy Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention: training to change attitudes and knowledge to increase oral and dental hygiene during pregnancy

Category

N/A

2

Description

Control group: Routine training in Mangahi

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Fatima Hospital

Full name of responsible person
Mojgan Faezi

Street address
Shahed University, opposite Holy shrine of Imam Khomeini, Khalij Fars Expressway, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University
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

Shahed University

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
Shahed University
Full name of responsible person
Mojgan Faezi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable