

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

The effect of educational program based on Pender's Health Promotion Model on oral health among pregnant women in Hamadan city

Protocol summary

Summary

The purpose of this study was to determine the effect of an educational intervention based on Pender's Health Promotion Model on oral health among pregnant women in Hamadan city. In this study 128 pregnant women from 8 health centers in Hamadan city were randomly allocated to intervention (4 health centers and 64 women) and control (4 health centers and 64 women) groups. Inclusion criteria: being satisfied to participate in the study, having an active health record in the health center, and being in the first trimester. Exclusion criteria: absence from educational sessions more than twice, migration, and ending the pregnancy during intervention. The main intervention included three 45- minute sessions and a booklet in order to provide information and motivation to change in Pender's model construct. After 45 days of last session, a reminder of 8 informational and motivational text messages was offered to women of intervention group during 4 days (9 am, and 7 pm). Information about the individual characteristics, constructs of Pender's Health Promotion Model, and women's oral health behaviors (brushing before sleeping, brushing after each meal, and brushing after eating sweets) was collected by questionnaire before intervention, immediately after sessions and 3 months after sessions in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013080212456N3**

Registration date: **2013-08-15, 1392/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-15, 1392/05/24

Registrant information

Name

Akram Karimi-Shahanjarini

Name of organization / entity

Hamedan University of Medical Science

Country

Iran (Islamic Republic of)

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+98 81 1838 0583

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karimi.a@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vic-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-02-23, 1391/12/05

Expected recruitment end date

2013-03-18, 1391/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of educational program based on Pender's Health Promotion Model on oral health among pregnant women in Hamadan city

Public title

Oral health and pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: being satisfied to participate in the

study; having an active health record in the health center, and being in the first trimester Exclusion criteria: absence from educational sessions more than twice; migration, and ending the pregnancy during intervention.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 128

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan University of Medical Science

Street address

Hamadan University of Medical Sciences, Shaheed

Fahmideh Ave Hamadan

City

Hamadan

Postal code

Approval date

2013-02-19, 1391/12/01

Ethics committee reference number

d/p/16/35/9/1051

Health conditions studied

1

Description of health condition studied

Pregnancy

ICD-10 code

Z80-99

ICD-10 code description

Persons with potential health hazards related to family and personal history and certain conditions influencing health status

Primary outcomes

1

Description

Perceived benefits

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

2

Description

Perceived barriers

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

3

Description

Perceived self efficacy

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

4

Description

Affect related to behavior

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

5

Description

Interpersonal influences

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

6

Description

Commitment to plan of action

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

7

Description

Pattern

Timepoint

Baseline, immediately after intervention and 3 months after intervention

Method of measurement

Questionnaire

8

Description

brushing before sleeping

Timepoint

Baseline, 3 months after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Brushing after each meal

Timepoint

Baseline, 3 months after intervention

Method of measurement

Questionnaire

2

Description

Brushing after eating sweets

Timepoint

Baseline, 3 months after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

The main intervention included three 45- minute sessions and a booklet in order to provide information and motivation to change in Pender's model construct. After 45 days of last session, a reminder of 8 informational and motivational text messages was offered to women of intervention group during 4 days (9 am, and 7 pm).

Category

Prevention

2

Description

Control group: no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Karrbasian

Full name of responsible person

Street address

City

Hamedan

2

Recruitment center

Name of recruitment center

Ghods

Full name of responsible person

Street address

City

Hamedan

3

Recruitment center

Name of recruitment center

Shohada

Full name of responsible person

Street address

City

Hamedan

4

Recruitment center

Name of recruitment center

Morad beyg

Full name of responsible person

Street address

City

Hamedan

5

Recruitment center

Name of recruitment center

Joulan

Full name of responsible person

Street address

City

Hamedan

6

Recruitment center

Name of recruitment center

Emam Hosein

Full name of responsible person

Street address

City

Hamedan

7

Recruitment center

Name of recruitment center

Sameei 3

Full name of responsible person

Street address

City

Hamedan

8

Recruitment center

Name of recruitment center

Sameei 10

Full name of responsible person

Street address

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences

Full name of responsible person

Dr Ahmad Tavilani

Street address

Hamedan University of Medical Sciences

City

Hamedan

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vic-chancellor of Research and Technology, Hamadan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Akram Karimi

Position

PhD, Assistant Professor

Other areas of specialty/work

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**Person responsible for scientific
inquiries**

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Person responsible for updating data

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Fax

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty