Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
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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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Position
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Phone
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Fax
Email
Web page address

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