

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of an educational program based on Pender's health promotion model on the frequency and duration of toothbrushing among pregnant women: Application of social networks

Protocol summary

Study aim

The effect of an educational program based on Pender's health promotion model on the frequency and duration of toothbrushing among pregnant women using social networks

Design

104 pregnant women who meet the inclusion criteria will be randomly assigned to intervention and control groups (control group: 52 and intervention group: 52). The pre-test will be completed by both groups. Three months after the intervention, the post-test will be completed in both groups.

Settings and conduct

The study will be conducted among pregnant women with records at Arak health centers. The intervention group will receive training through the social network. In the present study, blinding will be done regarding the participants and statistical investigator.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having a record in one of the health centers of Arak city, gestational age under 12 weeks, age between 16 and 46 years, ability to use social network
Exclusion criteria: abortion, premature birth, complicated problems during pregnancy, reluctance to continue participation in the study

Intervention groups

The intervention group will receive the educational program based on Pender's health promotion model for three months through social network. The control group will receive trainings on self-care during pregnancy.

Main outcome variables

toothbrushing behavior

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221228056955N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **prospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Maryam Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3727 5830

Email address

barati85@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-20, 1401/10/30

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of an educational program based on Pender's health promotion model on the frequency and duration of

toothbrushing among pregnant women: Application of social networks

Public title

The effect of educational program on oral health in pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having a pregnancy record in one of the health centers of Arak Gestational age under 12 weeks Age 16 to 46 years Ability to use social networks

Exclusion criteria:

Abortion Preterm birth complicated problems during pregnancy Reluctance to continue participation in the study

Age

From **16 years** old to **46 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the city of Arak is divided into five municipal districts, the health centers were also divided into five parts according to these districts. Some of the health centers were randomly selected from each of the districts depending on their scope and population. The selected centers were randomly assigned to the control group (20 centers) and the intervention group (19 centers). Finally, due to the small number of pregnant women in the first trimester in each center, pregnant women who meet the inclusion criteria will be included in the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study participants do not know that they were in the control or intervention groups. The statistical investigator do not know that the data is related to the control or intervention groups.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee of Hamadan University of Medical Sciences

Street address

Health Faculty, Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran.

City

Hamadan

Province

Hamadan

Postal code

8138380509

Approval date

2021-01-09, 1399/10/20

Ethics committee reference number

IR.UMSHA.REC.1399.863

Health conditions studied

1

Description of health condition studied

Oral health including the frequency and duration of tooth brushing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Constructs of Pender's Health Promotion Model

Timepoint

Before and three months after the intervention

Method of measurement

Researcher made questionnaire

Secondary outcomes

1

Description

Tooth brushing behavior including frequency and duration of tooth brushing

Timepoint

Before and three months after the intervention

Method of measurement

Researcher made questionnaire

Intervention groups

1

Description

Intervention group: In this study, educational

intervention will be done through social network. The educational intervention will be conducted from 12 to 28 weeks of pregnancy (3 months). Then the women will be followed up for 3 months.

Category

Behavior

2**Description**

Control group: The control group will receive the educational program including self-care during pregnancy (topics except oral hygiene and related issues) through social network.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Health center of Arak city

Full name of responsible person

Shariar Hoseini

Street address

Shahid Beheshti Phase 2, Hepko Street, Arak, Iran.

City

Arak

Province

Markazi

Postal code

3177-8-38189

Phone

+98 83 3313 9035

Fax**Email**

arakmarkazi@arakmu.ac.ir

Web page address

<https://arakmu.ac.ir/arakdh/fa/page/1927>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

Street address

Health Faculty, Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran.

City

Arak

Province

Markazi

Postal code

8138380509

Phone

+98 83 3727 5830

Email

Fanavari@umsha.ac.ir

Web page address

<https://research.umsha.ac.ir>

Grant name**Grant code / Reference number**

9904242558

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

Yes

Title of funding source

Hamedan 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**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Barati

Position

PhD student

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Health Faculty, Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran.
Postal Code: 8138380509

City

Hamadan

Province

Hamadan

Postal code

8138380509

Phone

+98 83 3727 5830

Fax

+98 83 3838 0509

Email

barati85@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Barati

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Maryam Barati, Health Faculty, Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran. Phone: +98 9186030112. barati85@gmail.com.

City

Hamadan

Province

Hamadan

Postal code

8138380509

Phone

+98 83 3727 5830

Fax

+98 83 3838 0509

Email

barati85@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Barati

Position

PhD student

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Health Promotion

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Data related to questionnaire and anonymous demographic information.

When the data will become available and for how long

Access to data after publication of results

To whom data/document is available

The data will be available for researchers.

Under which criteria data/document could be used

Using data to conduct meta-analysis studies

From where data/document is obtainable

The applicant can receive the data and documents by sending an email to barati85@gmail.com.

What processes are involved for a request to access data/document

After receiving the email and reviewing the request, the data will be available to the requester within a week.

Comments

No additional information