

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Effect of Social Marketing Based on Health Belief Model to Preventive Behavior of Tooth Decay among Pregnant Women in Health Centers in Mashhad

#### Protocol summary

##### Study aim

The aim of this study was to determine the effect of social marketing based on health belief model to preventive behavior of tooth decay among pregnant women.

##### Design

In this randomized clinical trial, 60 pregnant woman who referred to health Center No. 2 of Mashhad were chosen with available sampling method and were randomly divided into two groups of control and intervention.

##### Settings and conduct

This study was conducted on 60 pregnant woman who referred to health Center No. 2 of Mashhad that were randomly divided into two groups (n = 30).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age less than 24 weeks.  
Exclusion criteria: Not attending one of the training sessions.

##### Intervention groups

Intervention group: in intervention group, was conducted 3 educational sessions of 60 to 90 minutes for women.  
Control group: in control group, was conducted routine education of oral health for this period, too.

##### Main outcome variables

Knowledge of pregnant women  
Performance of pregnant women

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171130037690N1**  
Registration date: **2018-01-18, 1396/10/28**  
Registration timing: **retrospective**

Last update: **2018-01-18, 1396/10/28**

Update count: **0**

##### Registration date

2018-01-18, 1396/10/28

##### Registrant information

###### Name

Zahra Talaei manesh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3858 3868

###### Email address

talaeimz2@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2017-11-06, 1396/08/15

##### Expected recruitment end date

2018-01-05, 1396/10/15

##### Actual recruitment start date

2017-11-06, 1396/08/15

##### Actual recruitment end date

2018-01-05, 1396/10/15

##### Trial completion date

empty

##### Scientific title

The Effect of Social Marketing Based on Health Belief Model to Preventive Behavior of Tooth Decay among Pregnant Women in Health Centers in Mashhad

##### Public title

The Effect of Social Marketing to Preventive Behavior of Tooth Decay among Pregnant Women

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Gestational age less than 24 weeks  
Unemployment in dental care or health care jobs  
Not having advanced oral and dental disease  
Not having high risk pregnancy

### **Exclusion criteria:**

Not attending one of the training sessions

## **Age**

From **18 years** old to **35 years** old

## **Gender**

Female

## **Phase**

2-3

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **60**

Actual sample size reached: **60**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

The women divided to intervention and control group with simple randomization method.

## **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**

Ethics committee of Mashhad University of Medical Sciences

##### **Street address**

Mashhad University of Medical Sciences, Vice chancellor for research, Ghoraishy Building, University St

##### **City**

Mashhad

##### **Province**

Razavi Khorasan

##### **Postal code**

9137913316

#### **Approval date**

2017-11-05, 1396/08/14

#### **Ethics committee reference number**

IR.MUMS.REC.1396.186

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Knowledge

#### **ICD-10 code**

#### **ICD-10 code description**

### 2

#### **Description of health condition studied**

Practice

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

Knowledge

#### **Timepoint**

Before the intervention and the end of second week

#### **Method of measurement**

Oral Care in Pregnant Mothers based on Health Belief Model questionnaire

### 2

#### **Description**

Performance

#### **Timepoint**

Before the intervention and the end of second week

#### **Method of measurement**

Oral Care in Pregnant Mothers based on Health Belief Model questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: in intervention group, was conducted 3 educational sessions based health belief method (including 7 phases: 1- preliminary Planning, 2- consumer analysis, 3- market analysis, 4- channel analysis, 5- develop interventions and materials, 6- implementation and 7- evaluation) of 60 to 90 minutes of oral health for women.

#### **Category**

Prevention

### 2

#### **Description**

Control group: in control group, was conducted 3 routine educational sessions of 60 to 90 minutes of oral health (with face to face method) for women, too.

#### **Category**

Prevention

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Health Center No. 2

**Full name of responsible person**

Ali Asghar Mahmoudi

**Street address**

Woman Department, Health Center No. 2, Vahdat St,  
Mashhad

**City**

Mashhad

**Province**

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**Postal code**

9153913153

**Phone**

+98 51 3365 3000

**Email**

M2HCenter@mums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Mashhad University of Medical Sciences, Vice  
chancellor for research, Ghoraihy Building,  
University St

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Razavi Khorasan

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**Phone**

+98 51 3841 1538

**Email**

vcresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Talaei Manesh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Mashhad Faculty of Nursing and Midwifery, Ebn-e Sina  
St, Doktora Crossroads

**City**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Shahrokh Maghsoudi

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zahra Talaei Manesh

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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**Email**

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## Sharing plan

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of the participants' information

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The study report published in the dissertation form and article for researcher.

**When the data will become available and for how long**

The start of access is 6 months after the announcement of the results.

**To whom data/document is available**

Researchers at university centers

**Under which criteria data/document could be used**

Data is authorized only with permission from the author of the articles and with the source.

**From where data/document is obtainable**

Zahra Talaei Manesh, Emam Reza Hospital No. 2, Central Operation Room, Contact Number: 00989151579378, Email: talaeimz2@mums.ac.ir

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

After submitting a request, the request is reviewed and, if the request is accepted, is answered within 1 month.

**Comments**

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