# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Effects of an educational intevention in mothers on oral health of their 1-2 years children: Applying Theory of Planned Behavior (TPB) & Self Efficacy (SE)

## Protocol summary


**Summary**

Objectives: To assess the effect of educational program based on Theory of Planned Behavior (TPB) and self efficacy to modify mothers' behavior regard to oral health of 1-2 year children. Design: A randomized controlled trial. Setting and sampling: Overall, 90 eligible mothers from 10 daycare centers in Hamedan will be randomly allocated to intervention and control groups. Intervention: For mothers of intervention group three education sessions based on motivational interview principles will be hold during three weeks. Moreover, in order to change in variables of TPB, a booklet will be delivered to intervention group. A reminder of motivational message will be given to intervention group 45 days after the intervention. Main outcome measures: The outcomes of interest that will be assessed are as follows: knowledge, attitude, subjective norms, perceived behavioral control, self efficacy, and mothers' behaviors regard to children's teeth cleaning before bed. These variables will be measured at baseline, after intervention, and 3 months after the intervention


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013031712456N1**
Registration date: **2013-03-17, 1391/12/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2013-03-17, 1391/12/27

**Registrant information**

**Name**


Akram Karimi-Shahanjarini

**Name of organization / entity**

Hamedan University of Medical Science

**Country**

Iran (Islamic Republic of)

**Phone**

+98 81 1838 0583

**Email address**

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**

2013-02-18, 1391/11/30

**Expected recruitment end date**

2013-03-19, 1391/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of an educational intevention in mothers on oral health of their 1-2 years children: Applying Theory of Planned Behavior (TPB) & Self Efficacy (SE)

**Public title**

Effect of educational program on children's oral health

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria :mothers who having 1-2 years child, mothers who their child lives with their ; being volunteer to participate in the study and regular participation in the

educational sessions. Exclusion criteria: absence from educational session more than twice and changing the daycare centers.

**Age**
No age limit

**Gender**
Female

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **90**

**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**
University of Medical Sciences

**Street address**
Hamedan , Shaheed Fahmideh Ave

**City**
Hamedan

**Postal code**
65178

**Approval date**
2013-03-05, 1391/12/15

**Ethics committee reference number**
D/P/16/35/1/4545

## Health conditions studied

### 1

**Description of health condition studied**
lack of child's oral health after feeding

**ICD-10 code**
Z72.4

**ICD-10 code description**
Inappropriate diet and eating habits

## Primary outcomes

### 1

**Description**
Children's teeth cleaning after feeding before bed

**Timepoint**
Baseline,10 days and 3 months after intervention

**Method of measurement**
Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: no intervention.

**Category**
N/A

### 2

**Description**
Intervention group: Three educational sessions based on motivational interview principles, a booklet about basic information and skills of children' oral health and persuasive massages in order to change in variables of TPB

**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Khorshid center

**Full name of responsible person**

**Street address**

**City**
Hamedan

### 2

**Recruitment center**

**Name of recruitment center**
Shahid Rajaee center

**Full name of responsible person**

**Street address**

**City**
Hamedan

### 3

**Recruitment center**

**Name of recruitment center**
Faraz center

**Full name of responsible person**

**Street address**

**City**

Hamedan

**4**

**Recruitment center**
**Name of recruitment center**
Rangin Kaman center
**Full name of responsible person**
**Street address**
**City**
Hamedan

**5**

**Recruitment center**
**Name of recruitment center**
Golhay Zendegi center
**Full name of responsible person**
**Street address**
**City**
Hamedan

**6**

**Recruitment center**
**Name of recruitment center**
Neshat center
**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**
از محل يك درصد بودجه طرح‌هاي تحقيقاتي دانشگاه
**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-Shahanjarini
**Position**
PhD, Assistant Professor
**Other areas of specialty/work**
**Street address**
School of Public Health, Hamadan University of Medical Sciences, Shaheed Fahmideh Ave
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*