

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of an educational intervention 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 intervention 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 Rajaei 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 طرح هاي 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

City

Hamedan

Postal code

Phone

+98 81 1838 0509

Fax

Email

karimi.a@umsha.ac.ir

Web page address

Person responsible for scientific 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.

City

Hamedan

Postal code

Phone

+98 81 1838 0583

Fax

Email

karimi.a@umsha.ac.ir

Web page address

Person responsible for updating data

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

City

Hamedan

Postal code

Phone

+98 81 1838 0509

Fax

Email

Karimi.a@umsha.ac.ir

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