

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Clinical Trial comparative study of the effect of gain-framed and loss-framed messages on the knowledge and practice of mothers of children under 6 years old in the field of oral health

Protocol summary

Summary

The aim of this intervention study is to compare the effect of gain-framed and loss-framed messages on knowledge and practice of mothers of children under 6 years old in the field of oral health. The study population consists of all mothers with children less than 6 years. The inclusion criteria are having mobile phone and being literate and the exclusion criteria are having a mentally or physically disabled child and being educated in the field of studies related to dental health or dentistry. The sample (n=240) will be selected based on randomized cluster sampling and randomly allocated to three groups including intervention 1, intervention 2 and control group. In order to oral health education to mothers of children under 6 years old, in intervention 1 group gain-framed and in the intervention 2 group loss-framed SMS will be sent. So that within a month, 30 messages for each of the intervention groups 1 and 2 will be sent. Gain-framed messages focused on the benefits of compliance oral hygiene and loss-framed messages focused on disadvantages of non-compliance. The control group would not receive any intervention. To collect data, 2 knowledge and practice questionnaires will be used that developed by the researchers. Data will be collected before and 3 to 4 weeks after completion of the intervention. Expected outcome is the difference in the knowledge and practice of mothers in the three studied groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042727647N1**
Registration date: **2016-07-05, 1395/04/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-05, 1395/04/15

Registrant information

Name

Fatemeh Khademian

Name of organization / entity

School of Management and Medical Informatics,
Shiraz University of Medical Sciences, Shiraz, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial comparative study of the effect of gain-framed and loss-framed messages on the knowledge and practice of mothers of children under 6 years old in the field of oral health

Public title

The effect of gain-framed and loss-framed messages on the knowledge and practice of mothers of children under 6 years old in the field of oral health

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Have a mobile phone; Be literate; Have the ability to read Short Message Service (SMS); Have at least one child under 6 years; Wish to participate in the study. Exclusion criteria: Have education in the field of studies related to dental health or dentistry; Have a mentally or physically disabled child; Be excluded during the study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The sample will be selected by random cluster sampling. In this case, Shiraz city is divided into two parts of north and south geographical areas. Then 3 center from the list of the kindergartens of the north and 3 centers from the list of the kindergartens of the south will be selected based on simple random sampling. Afterwards, each kindergarten will be allocated to one of the intervention 1, intervention 2 and control groups based on simple random sampling.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Av, The Central Building of Shiraz University of Medical Sciences, Shiraz, Iran

City

Shiraz

Postal code

14336 - 71348

Approval date

2016-06-06, 1395/03/17

Ethics committee reference number

IR.SUMS.REC.1395.40

Health conditions studied**1****Description of health condition studied**

Dental caries

ICD-10 code

K02.9

ICD-10 code description

Dental caries, unspecified

Primary outcomes**1****Description**

Knowledge of oral health

Timepoint

Before the intervention, 3 to 4 weeks after completion of the intervention

Method of measurement

Knowledge of Oral Health Questionnaire

2**Description**

Practice of oral health

Timepoint

Before the intervention, 3 to 4 weeks after completion of the intervention

Method of measurement

Practice of Oral Health Questionnaire

Secondary outcomes**1****Description**

Visiting the dentist

Timepoint

Before the intervention, 3 to 4 weeks after completion of the intervention

Method of measurement

Practice of Oral Health Questionnaire

Intervention groups**1****Description**

Intervention group 1: Thirty gain-framed messages will be sent to the intervention groups 1 during one month. These messages focused on the benefits of compliance of oral hygiene.

Category

N/A

2**Description**

Intervention groups 2: Thirty loss-framed messages will be sent to the intervention groups 2 during one month. These messages focused on the disadvantages of non-compliance of oral hygiene.

Category

N/A

3**Description**

Control group: The control group did not receive any intervention.

Category

N/A

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

Nemazee Hospital Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

Nemazee Hospital, Nemazee Square, Zand Av, Shiraz, Iran

City

Shiraz

2**Recruitment center****Name of recruitment center**

Negar Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

Doostan Av, Maaliabad, Shiraz, Iran

City

Shiraz

3**Recruitment center****Name of recruitment center**

Ghonchehaye Behesht Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

14 Alley, Jomhoori Boulevard, Shiraz, Iran

City

Shiraz

4**Recruitment center****Name of recruitment center**

Ayeha Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

Zeinabiyeh Hospital, Khatoon Square, Shiraz, Iran

City

Shiraz

5**Recruitment center****Name of recruitment center**

Shahre Raz Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

Front of Narjes Sports Complex, Razi Boulevard, Shiraz, Iran

City

Shiraz

6**Recruitment center****Name of recruitment center**

Afarin Kindergarten

Full name of responsible person

Fatemeh Khademian

Street address

Golestan Boulevard, Golestan Square, Shiraz, Iran

City

Shiraz

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

Vice Chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Khademian

Street address

School of Management and Medical Informatics, Almas Building, Allay 29, Qasrodasht Av, Shiraz, Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research of Shiraz 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

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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