

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluating the effect of educational pamphlets on parents' knowledge of fluoride and fluoride-containing products and their role in oral health among parents of 7-12-year-old children.

Protocol summary

Study aim

Considering the high prevalence of dental caries among the children of Iran, conducting studies to increase parents' knowledge of caries preventive procedures, especially fluoride can effectively decrease the rate of dental caries. Also, Evaluating the effect of educational pamphlets, as a tool for teaching parents, can be helpful in utilizing the best method to increase their knowledge. In conclusion, this study aims to determine the effect of educational pamphlets on parents' knowledge of fluoride and fluoride-containing products and their role in oral health among parents of 7-12-years-old children.

Design

Pre-test post-test design

Settings and conduct

In this study, parents of 7-12-years-old children will be chosen from one boy's and one girl's school in each district of Rasht. Then written consent will be obtained and a researcher-made questionnaire will be given to parents to fill out with their current knowledge of fluoride. Afterward, the educational pamphlets will be given to the parents to read. Finally, the pamphlets are collected. In a one-month period the parents will fill out the same questionnaire and the final data will be collected and analyzed.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: parents of 7-12-years-old children
Non-inclusion criteria: parents, who are not willing to participate

Intervention groups

No control group is considered for this study. Firstly the primary Data of parents' knowledge will be collected through a researcher-made questionnaire. Then the educational pamphlets will be given to the parents to read. Finally, in a one-month period, parents will fill out the same questionnaire and the secondary Data will be collected.

Main outcome variables

The amount of increase in parents' knowledge after reading the pamphlets and by number of children, order of children, parents education. parents' age and mother's occupational status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230904059354N1**

Registration date: **2023-09-08, 1402/06/17**

Registration timing: **prospective**

Last update: **2023-09-08, 1402/06/17**

Update count: **0**

Registration date

2023-09-08, 1402/06/17

Registrant information

Name

Hossein Esmailpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3200 7546

Email address

mesbahep99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of educational pamphlets on parents' knowledge of fluoride and fluoride-containing products and their role in oral health among parents of 7-12-year-old children.

Public title

How effective are the educational brochures in increasing parents' knowledge about fluoride

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Parents of 7-12-years-old children

Exclusion criteria:

Parents, who are not willing to participate in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 122

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

Somayeh Boulevard, 122 Street, Aftabgardan Alley

City

Rasht

Province

Guilan

Postal code

4165953897

Approval date

2023-08-19, 1402/05/28

Ethics committee reference number

IR.GUMS.REC.1402.274

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

knowledge of Fluoride and Fluoride-containing products and its role in Oral Health

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Knowledge score based on a researcher-made questionnaire

Timepoint

Knowledge score at the beginning of the study and one month after the intervention

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

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

Intervention group: Only one intervention group is considered in this study. In this group, educational pamphlets will be handed to parents to read after collecting the primary data. The pamphlet is designed by the researcher. It contains brief information about Fluoride and Fluoride therapy, Fluoride natural sources, Tap water fluoridation, Over-the-Counter Fluoride sources such as toothpaste and mouthwash and how to use them, and also the sources that need prescription such as Fluoride supplements. parents should read the pamphlets in the same session that the primary data is collected.

Category

Prevention

Recruitment centers**1****Recruitment center**

Name of recruitment center

Baran Andishe Elementary School
Full name of responsible person
Zahra Nazari Rad
Street address
Emdad alley, Golbagh Namaz Ave
City
Rasht
Province
Guilan
Postal code
4165953897
Phone
+98 13 3375 9771
Email
mesbahep99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyed Sana Alavi Niako
Street address
Gilan Province, Fouman - Saravan Rd, Guilan
Academic Complex of Medical Sciences
City
Rasht
Province
Guilan
Postal code
4194173774
Phone
+98 13 3348 6406
Email
alaviniakoo@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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
Rasht University of Medical Sciences

Full name of responsible person

Hossein Esmailpour

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

122 Street

City

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Phone

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mesbahep99@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Leila Simaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Gilan Province, Fouman - Saravan Rd, Guilan
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Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Hossein Esmailpour

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry
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122 Street
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Fax
Email
mesbahep99@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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 amount of increase in knowledge after making data
unidentifiable Consent letter content questionnaire and
pamphlet content

When the data will become available and for how long

6 months after publish of the results until 1 year and 6
months after it

To whom data/document is available

researchers, who are occupied in higher education
institutes

Under which criteria data/document could be used

usable in Review studies

From where data/document is obtainable

contact the researcher mesbahep99@gmail.com

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

It will be checked by the research and if approved, it will
be available for them

Comments