

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Comparative study between the effect of Motivational Interviewing and common dental health education for mothers on the oral hygiene of under 6-year-old leukemic children

Protocol summary

Study aim

Comparison between the effect of Motivational Interviewing and common dental health education for mothers on the oral hygiene of under 6-year-old leukemic children

Design

randomized, blinded, controlled clinical trial with a parallel group design of 56 patients

Settings and conduct

Motivational Interviewing Method compares with common oral health teaching methods. The study is conducted in the MAHAK Pediatric Cancer Treatment & Research Center. Mothers are assigned randomly, to either common teaching methods group or Motivational Interviewing group. Before receiving the teaching method, with the help of the mothers of both groups, the knowledge, the attitude and practice questionnaire are completed. The microbial plaque index is also examined and recorded on children's teeth. After three months, the previous questionnaire is filled out again by mothers. The plaque index is evaluated. One researcher gives pre-test and post-test questionnaires to mothers and a second researcher performs statistical analysis. Both researchers are blind to the allocation of participants to groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children under 6 years old; Children on the primary stage of cancer and treated by chemotherapy; Have consent for participation; Mothers with minimum ability to read and write; Mothers who are the main caregiver of the child in the family. Exclusion criteria: Children who have systemic diseases and intellectual disability; children with acute Leukemia.

Intervention groups

Control group: Mothers who receive common teaching methods. Intervention group: Mothers who receive motivational interviewing protocol about child oral health.

Main outcome variables

Change in knowledge, attitude and practice of mothers.
Change in plaque index of child.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131102015238N5**

Registration date: **2021-03-11, 1399/12/21**

Registration timing: **prospective**

Last update: **2021-03-11, 1399/12/21**

Update count: **0**

Registration date

2021-03-11, 1399/12/21

Registrant information

Name

Simin Z. Mohebbi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 5960

Email address

smohebbi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-09, 1400/01/20

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparative study between the effect of Motivational Interviewing and common dental health education for mothers on the oral hygiene of under 6-year-old leukemic children

Public title
Evaluating the effect of Motivational Interviewing in children with cancer oral hygiene and comparing with common teaching methods

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Children under 6 years old. Children on the primary stage of cancer and treated by chemotherapy Have consent for participation Mothers with minimum ability to read and write Mothers who are the main caregiver of the child in the family.
Exclusion criteria:
Children who have systemic diseases and intellectual disability Children with acute Leukemia

Age
To 6 years old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: 56

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization method, using an Excel spreadsheet. In the Excel spreadsheet the leftmost column shows the total number of participants, which in the current study will be 56. First we arrange the random numbers then in ascending order. The next column indicates the group to which participants belong, with the top half in Group A and the bottom half in Group B. For the next column is filled using the "Rand" function; this function generates random numbers for all individuals, so the individuals will be randomly ordered within each of the two groups. At the end they enter the study according to the order of referral and allocate a code to them. Random unit: individual Randomization Tool: Software

Blinding (investigator's opinion)
Double blinded

Blinding description
The information about the assignment of each participant to the study groups is coded and through

this, the research facilitators, evaluators of the results and statistical analysts are blind to it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Number 2, Dolatshahi alley, Naderi street, Keshavarz Boulvar, Virtual faculty
City
Tehran
Province
Tehran
Postal code
1417614418

Approval date
2021-01-30, 1399/11/11

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1399.208

Health conditions studied

1

Description of health condition studied
oral hygiene of leukemic children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mother's score in knowledge, attitude, and practice questionnaire

Timepoint
Before the intervention, three months after the intervention

Method of measurement
Knowledge, attitude and practice questionnaire on oral health

2

Description
Microbial Plaque

Timepoint

Before the intervention, three months after the intervention

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mothers who receive motivational interviewing protocol about child oral health that Includes 5 stage and Dental Health Menu including information about oral health which mothers can choose any number of them. two phone call follow up appointment should be done two weeks and one month after intervention for answering questions.

Category

Lifestyle

2

Description

Control group: Mothers who receive common teaching method Including a pamphlet about oral health and a brief verbal explanation.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

MAHAK Pediatric Cancer Treatment & Research Center

Full name of responsible person

Simin Z. Mohebbi

Street address

MAHAK Pediatric Cancer Treatment & Research Center, MAHAK Blvd., Prof. Parvaneh Vossough St., Shahid Majdi Blvd., Artesh Freeway, Tehran – Iran

City

Tehran

Province

Tehran

Postal code

۱۹۵۶۹۹۳۴۶۱

Phone

+98 21 2350 1000

Email

smohebbi@tums.ac.ir

Web page address

<https://mahak-charity.org/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Simin Z. Mohebbi

Street address

End of kargar Street

City

Tehran

Province

Tehran

Postal code

1439955991

Phone

+98 21 8801 5960

Email

smohebbi@tums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Simin Z. Mohebbi

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

Street address

End of kargar Street

City

Tehran

Province

Tehran

Postal code

1439955991

Phone
+218 8015960
Fax
+98 21 8801 5961
Email
smohebbi@tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Simin Z. Mohebbi
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Dentistry
Street address
End of Kargar Street
City
Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 8801 5960
Fax
+98 21 8801 5961
Email
smohebbi@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Simin Z. Mohebbi
Position
Faculty member
Latest degree
Ph.D.
Other areas of specialty/work
Dentistry
Street address
End of Kargar Street

City
Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 8801 5960
Fax
+98 21 8801 5961
Email
smohebbi@tums.ac.ir

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

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

All the study findings will be shared after identifying people for public view in Tehran University of Medical Sciences program, Mahak hospital, and other cancer centers in Iran.

When the data will become available and for how long

The start of the data access period is 6 months after the results are published.

To whom data/document is available

All the study findings will be shared for public view in Tehran University of Medical Sciences program, Mahak hospital, and other cancer centers in Iran.

Under which criteria data/document could be used

.All the study findings could be used for improving children's oral health status in all cancer centers in Iran.

From where data/document is obtainable

Correspondent: Simin Z. Mohebbi Email: smohebbi@tums.ac.ir Phone: +218 8015960

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

Email the correspondent for receiving documents.

Comments