Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Designing, implementation and evaluation of a mother-centered educational program based on the PRECED- PROCEED model, to improve oral health of Afghan immigrant children aged 6 to 12 living in the refugee camp of Rafsanjan and Bardsir in Kerman province in 2025-2026

Protocol summary

Study aim
Improving the oral health of Afghan immigrant children through mother-centered education

Design
This quasi-experimental controlled trial with parallel groups and open-label design includes 190 children per group (380 total) calculated based on design effect and 20% attrition. Randomization is performed at the camp level, where two camps are randomly allocated using a computer. Eligible participants are then identified through the SIB system, and simple random sampling using a computer will be employed.

Settings and conduct
The study is conducted in two camps (Rafsanjan, Bardesir). After needs assessment, intervention packages are developed. The intervention group receives education and in-person follow-ups; the control group receives routine services only. Data are collected via questionnaires and clinical exams at baseline, 2 months, and 6 months post-intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Informed consent from the mother (and father for the child), at least 6 months of residency in the refugee camp, having at least one child aged 6 to 12 years in the family, and no plan to leave the camp within the next year. Exclusion criteria: Presence of any specific physical, motor, neurological, or psychiatric illness in any family member that would disrupt the study process.

Intervention groups
Based on the needs assessment results, intervention packages will be developed, which may include mother-specific content (e.g., clips, brochures, short lectures) and child-specific content (e.g., films, video clips, games, interactive educational cards) along with provision of toothbrushes and dental floss; additionally, in-person follow-ups and weekly reminder text messages will be conducted.

Main outcome variables
Scores of predisposing, enabling, and reinforcing factors; Gingival Index (GI); Simplified Oral Hygiene Index (OHI-S).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260210068827N1**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date
2026-05-11, 1405/02/21

Registrant information

Name
Amin Arsalan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2027-01-05, 1405/10/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Designing, implementation and evaluation of a mother-centered educational program based on the PRECED-PROCEED model, to improve oral health of Afghan immigrant children aged 6 to 12 living in the refugee camp of Rafsanjan and Bardsir in Kerman province in 2025-2026

Public title
The effect of oral health education for Afghan mothers on the oral health of their 6- to 12-year-old children in Rafsanjan and Bardsir
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Obtaining informed consent from the mother for her participation in the study. Obtaining informed consent from both the mother and the father for the participation of their child or children in the study. Having at least one child between 6 and 12 years of age. Having resided in the refugee camp for a minimum of six months. Having no plan to leave the refugee camp within the next year.
Exclusion criteria:
Any specific physical, motor, or mental-psychological illness of any family member that disrupts the study process. Mothers and children who complete the initial checklist in the form of a needs assessment in the third stage of the first part of the study will not be entered into the trial section of the study.
Age
From **6 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **760**
Randomization (investigator's opinion)
Randomized
Randomization description
Due to the presence of only two refugee camps in Kerman province, group allocation is performed as cluster randomization. Using a computer and simple randomization method, one camp is designated as the intervention group and the other as the control group. Subsequently, within each camp, eligible participants (mothers and children aged 6 to 12 years) are selected through simple random sampling using random numbers generated by a computer via the "SIB" integrated health system.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The intervention implementation phase is conducted as a quasi-experimental trial. Since there are only two refugee camps in Kerman province and individual-level random allocation is not feasible, the present study is designed as a quasi-randomized controlled trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences, School of Dentistry, Ethics Committee
Street address
North Kargar Street, before Hakim Expressway, Tehran School of Dentistry۱۴
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۹۵۵۹۳۴
Approval date
2024-11-13, 1403/08/23
Ethics committee reference number
IR.TUMS.DENTISSTRY.REC.1403.090

Health conditions studied

1

Description of health condition studied
Dental Caries
ICD-10 code
K02
ICD-10 code description
Dental caries

2

Description of health condition studied
Periodontal diseases
ICD-10 code
K05
ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description

Mean changes in the Simplified Oral Hygiene Index (OHI-S) in Afghan children aged 6-12 years

Timepoint

In this study, the time points for measuring the primary outcome variable (mean changes in the OHI-S index) include before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention.

Method of measurement

This index is assessed through clinical examination using a dental mirror, dental explorer, and Williams periodontal probe, under artificial light and on a dental unit. The Simplified Oral Hygiene Index consists of two components: the Debris Index and the Calculus Index. For this purpose, six index teeth including teeth numbers 16, 11, 26, 36, 31, and 46 are examined. Each tooth is scored from zero to three, and the sum of the Debris Index and Calculus Index scores divided by the number of teeth examined is considered as the final score of the Simplified Oral Hygiene Index. These examinations are performed by the researcher (PhD student in Community Oral Health and Dental Social Medicine) based on the World Health Organization criteria. Additionally, before starting the study, the examiner will be calibrated with a specialist dentist, and the inter-rater agreement will be calculated.

Secondary outcomes

1

Description

Mean changes in the Gingival Index in Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

This index is assessed through clinical examination using a dental mirror, dental explorer, and Williams periodontal probe, under artificial light and on a dental unit. The Simplified Oral Hygiene Index consists of two components: the Debris Index and the Calculus Index. For this purpose, six index teeth including teeth numbers 16, 11, 26, 36, 31, and 46 are examined. Each tooth is scored from zero to three, and the sum of the Debris Index and Calculus Index scores divided by the number of teeth examined is considered as the final score of the Simplified Oral Hygiene Index. These examinations are performed by the researcher (PhD student in Community Oral Health) based on the World Health Organization criteria. Additionally, before starting the study, the examiner will be calibrated with a Community Oral Health specialist, and the inter-rater agreement will be calculated.

2

Description

Mean changes in the Gingival Index in Afghan children aged 6-12 years

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The Gingival Index is assessed through clinical examination using a Williams periodontal probe, dental mirror, and dental explorer, under artificial light and on a dental unit. For this purpose, four areas (facial, distal, mesial, and lingual gingiva) are examined on index teeth including teeth numbers 16, 22, 24, 36, 32, and 44. The Gingival Index is graded as score zero (healthy gingiva), one (mild inflammation: slight change in gingival color accompanied by edema and no bleeding on probing), two (moderate inflammation: redness, edema, and gingival glossiness accompanied by bleeding on probing), and three (severe inflammation: redness and edema accompanied by ulceration with a tendency to spontaneous bleeding). The mean of the scores of the four areas is calculated as the Gingival Index score for each tooth, and the mean of the tooth scores is considered as the Gingival Index score for each person. The examinations are performed by the researcher (PhD student in Community Oral Health) based on the World Health Organization criteria.

3

Description

Mean changes in the Gingival Index in Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The Gingival Index is assessed through clinical examination using a Williams periodontal probe, dental mirror, and dental explorer, under artificial light and on a dental unit. For this purpose, four areas (facial, distal, mesial, and lingual gingiva) are examined on index teeth including teeth numbers 16, 22, 24, 36, 32, and 44. The Gingival Index is graded as score zero (healthy gingiva), one (mild inflammation: slight change in gingival color accompanied by edema and no bleeding on probing), two (moderate inflammation: redness, edema, and gingival glossiness accompanied by bleeding on probing), and three (severe inflammation: redness and edema accompanied by ulceration with a tendency to spontaneous bleeding). The mean of the scores of the four areas is calculated as the Gingival Index score for each tooth, and the mean of the tooth scores is considered as the Gingival Index score for each person. The examinations are performed by the researcher (PhD student in Community Oral Health) based on the World Health Organization criteria.

4

Description

Mean changes in the oral health-related quality of life score in Afghan mothers

Timepoint

Before the intervention (Baseline)

Method of measurement

The oral health-related quality of life score is measured using a standardized and validated Persian questionnaire (the short version of the Oral Health Impact Profile questionnaire with 14 questions), which is completed by Afghan mothers. This questionnaire includes questions regarding the effects of oral health status on the ability to perform daily activities, physical disorders (such as difficulty in chewing, speaking, swallowing), psychological disorders (such as self-confidence, self-esteem, depression, anxiety, stress), and social disorders (such as absenteeism from work and school, academic performance). The questionnaire is completed by the researcher or research assistant (one of the trained health liaisons residing in the refugee camp) through questioning the mother.

5

Description

The mean changes in predisposing factors (knowledge, attitude, and self-efficacy) among Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The method of measuring the mean changes in the score of predisposing factors (knowledge, attitude, and self-efficacy) in Afghan mothers is as follows: a researcher-made structured questionnaire is used. This questionnaire is designed based on the constructs of the PRECEDE-PROCEED model and is developed after confirming its face and content validity and reliability (by calculating Cronbach's alpha coefficient). The questionnaire is completed by Afghan mothers in three time points (before the start of the intervention, two months after the start of the intervention, and six months after the start of the intervention) with the assistance of the researcher or a trained assistant (from among the health liaisons residing in the refugee camp). The score of each component of knowledge, attitude, and self-efficacy is calculated separately, and then the overall score of predisposing factors is obtained by summing or averaging these three components. Finally, the mean changes in these scores in each group (intervention and control) are calculated by comparing the scores at different time points and are compared between the two groups using analysis of covariance (ANCOVA).

6

Description

The mean changes in enabling factors scores among Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The mean changes in the score of predisposing factors (knowledge, attitude, and self-efficacy) in Afghan mothers are measured using a researcher-made structured questionnaire that is designed and developed based on the constructs of the PRECEDE-PROCEED model. The process of developing this questionnaire is such that, initially, based on the literature review and the results of the third phase of the study (educational and ecological assessment), items related to each of the components of knowledge, attitude, and self-efficacy are extracted. Then, the face and content validity of the questionnaire is assessed using expert opinions and statistical methods such as test-retest, and its reliability is confirmed by calculating Cronbach's alpha coefficient. The final questionnaire is completed by Afghan mothers in three time points with the assistance of the researcher or a trained assistant (one of the health liaisons residing in the refugee camp). Each response is assigned a specific numerical score, and the score of each component (knowledge, attitude, and self-efficacy) is calculated separately. Finally, the overall score of predisposing factors is obtained by summing or averaging the scores of these three components, and the mean changes in each group (intervention and control) are calculated by comparing the scores at different time points and are compared between the two groups using analysis of covariance (ANCOVA).

7

Description

Mean changes in the score of reinforcing factors in Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The mean changes in the score of reinforcing factors in Afghan mothers are measured using a researcher-made structured questionnaire that is designed and developed based on the constructs of the PRECEDE-PROCEED model. Reinforcing factors include factors that lead to the continuation of behavior and provide continuous rewards for maintaining behavior, such as family support (especially mothers as the main reinforcing factor). Initially, based on the literature review and the results of the third phase of the study (educational and ecological assessment), items related to each of the components of reinforcing factors are extracted. Then, the face and content validity of the questionnaire is assessed using expert opinions and statistical methods, and its reliability is confirmed by calculating Cronbach's alpha coefficient. The final questionnaire is completed by Afghan mothers in three time points with the assistance of the researcher or a trained assistant (one of the health liaisons residing in the refugee camp). Each response is assigned a specific numerical score, and the overall score of

reinforcing factors is calculated by summing or averaging the scores of the relevant items. Finally, the mean changes in these scores in each group (intervention and control) are calculated by comparing the scores at different time points and are compared between the two groups using analysis of covariance.

8

Description

Mean changes in the score of behavior (performance) in Afghan mothers

Timepoint

Before the intervention (baseline), 2 months after the start of the intervention, and 6 months after the start of the intervention

Method of measurement

The mean changes in the score of behavior (performance) in Afghan mothers are measured using a researcher-made structured questionnaire that is designed and developed based on the constructs of the PRECEDE-PROCEED model. Behavior (performance) includes the practical actions of the mother regarding the oral health care of herself and her children. The process of developing this questionnaire is based on the literature review and the results of the third phase of the study (educational and ecological assessment), items related to each of the components of behavior are extracted. Then, the face and content validity of the questionnaire is assessed using expert opinions and statistical methods, and its reliability is confirmed by calculating Cronbach's alpha coefficient. The final questionnaire is completed by Afghan mothers in three time points with the assistance of the researcher or a trained assistant (one of the health liaisons residing in the refugee camp). Each response is assigned a specific numerical score. The overall score of behavior (performance) is calculated by summing or averaging the scores of the relevant items. Finally, the mean changes in these scores in each group (intervention and control) are calculated by comparing the scores at different time points and are compared between the two groups using analysis of covariance.

Intervention groups

1

Description

Intervention group: A mother-centered educational program based on the PRECEDE-PROCEED model is implemented over a period of six months. The educational content is designed based on the results of the needs assessment phase and includes two packages: Package for children aged 6-12 years: Educational videos and clips with songs and stories, illustrated brochures, drawing activities, coloring charts, interactive game cards, age-appropriate toothbrush and dental floss for the child. Package for mothers: Educational clips and videos, simple and understandable brochures (suitable for illiterate individuals), short lecture sessions on proper tooth brushing and flossing techniques, and provision of toothbrush and dental floss for the mother. Implementation method: After inviting the mother and child to the comprehensive health center and completing the examinations, the packages are delivered to them. Trained health liaisons visit the homes during the first and second weeks after the start of the intervention, answering any questions. Additionally, reminder text messages are sent once a week for one month. All content is designed to be usable for mothers with low literacy or illiterate mothers.

Category

Prevention

2

Description

Control group: The control group receives no specific educational intervention beyond the routine program of the refugee camp. After being selected and providing informed consent, individuals in this group are invited to the comprehensive health center of the refugee camp at a scheduled time. Questionnaires and clinical examinations, similar to those of the intervention group, are completed for them at three time points (before the intervention, two months after the start of the study, and six months after the start of the study). During the study period, only the usual recommendation for oral health care (such as tooth brushing and flossing) is provided verbally and in a general manner to individuals in this group. At the end of the study, all educational content prepared for the intervention group will also be provided to the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rafsanjan Refugee Camp

Full name of responsible person

Ali Malakooti

Street address

Rafsanjan Refugee Camp, beginning of Police Boulevard, Persian Gulf Highway

City

Rafsanjan

Province

Kerman

Postal code

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Phone

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Email

arsalan59a@gmail.com

2

Recruitment center

Name of recruitment center

Bardsir Refugee Camp

Full name of responsible person
Ahmad Salari

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Bardsir Refugee Camp, Bidkhan Road

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Bardsir

Province
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Email
Bardsir.r.camp@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

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Province
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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
Amin Arsalan

Position
PhD student in Community Oral Health and Dental Social Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
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Position
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Social Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

School of Dentistry, Tehran University of Medical Sciences, before the exit of Hakim Expressway East, End of North Kargar Street

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The publication of this information requires permission from the University of Medical Sciences and the United Nations High Commissioner for Refugees.

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

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

All study data, including statistical data, analysis codes, and other trial-related data, will be reported in the dissertation and subsequent articles. The informed consent form will be published during the patient recruitment phase.

When the data will become available and for how long

10 months after the completion of the trial

To whom data/document is available

The data will only be made available to academic researchers.

Under which criteria data/document could be used

It is used only for assistance in academic research and is not permitted otherwise.

From where data/document is obtainable

Corresponding author and principal investigator

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

After contacting the corresponding author or principal investigator via email, a response will be provided within ten days via email.

Comments