

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating an oral and dental hygiene education based on motivational interviewing in patients with fixed orthodontic appliances

Protocol summary

Study aim

Comparison of plaque index and Gingival index before and after the intervention in 12-16 year old patients undergoing orthodontic treatments referred to the orthodontic department of Tehran University of Medical Sciences

Design

Clinical trial phase 2 without control group, non-randomly, no blinding, on 30 patients

Settings and conduct

Participants will receive verbal instructions during a 20-minute motivational interview with a final year dental student, as well as instruction on how to properly brush and floss on the model. Along with personal advice on how plaque forms, the importance of oral health behaviors, caries, gingivitis and ways to control them, as well as nutritional information related to oral health. At the end, a pamphlet containing the material presented is given to patients. For currencies, PI, GI, demographic information and oral health habits (including daily brushing, frequency of floss, frequency of using sweet snacks per day) before and 1 month after the intervention will be recorded. Patients' motivation is strengthened 3 times in 1 month by phone call. Study place: Orthodontics Department, Dental school, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients referred to the orthodontic department of the School of Dentistry of Tehran University of Medical Sciences, who were in the age range of 12 to 16 years, patients participated in the study voluntarily, signing Consent by parents. Conditions of absence: had a physical disability, had a systemic or underlying disease which affect gingiva or teeth or was taking certain medications

Intervention groups

oral hygiene education based on motivational interviewing

Main outcome variables

Brushing at least twice a day; Flossing at least once a day; Sweet snacks less than twice a day; At least 0.4 difference in plaque index; At least 0.5 difference in gingival index; Good/excellent gingival status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201031049204N1**

Registration date: **2020-11-02, 1399/08/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-02, 1399/08/12**

Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Shima Ziari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 1058

Email address

shimaziari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating an oral and dental hygiene education based on motivational interviewing in patients with fixed orthodontic appliances

Public title

Evaluating oral and dental hygiene education based on motivational interviewing in Orthodontic.

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients referred to the orthodontic department of the School of Dentistry of Tehran University of Medical Sciences who were in the age range of 12 to 16 years. Patients participate in the study voluntarily. signing Consent by parents

Exclusion criteria:

They had a physical disability. having systemic or underlying disease witch causing gingival or dental problems taking certain medications

Age

From **12 years** old to **16 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

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 Tehran University of Medical Sciences

Street address

Tehran University Dental School, after Atomic

Energy,North Kargar St. Tehran Town

City

Tehran

Province

Tehran

Postal code

1439955991

Approval date

2020-07-05, 1399/04/15

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1399.042

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

patients undergoing fixed orthodontics

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

changing gingival index with a predetermined criterion of 0.5 unit

Timepoint

Registration of gingival index before and 1 month after the intervention

Method of measurement

Examination and registration of clinical index

2**Description**

changing of plaque index with a predetermined criterion of 0.4 unit

Timepoint

Registration of plaque index before and 1 month after the intervention

Method of measurement

Examination and registration of clinical index

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

brushing time with a predetermined standard at least twice a day

Timepoint

record the number of brushing times before and 1 month after intervention

Method of measurement

oral health information checklist

2**Description**

flossing with a predetermined standard at least twice a

day

Timepoint
record the number of flossing before and 1 month after intervention

Method of measurement
oral health information checklist

3

Description
frequent consumption of sweet snacks with a predetermined standard up to twice a day

Timepoint
record the number of using sweet snacks before and 1 month after intervention

Method of measurement
oral health information checklist

4

Description
gingival inflammation status with a predetermined standard well/good.

Timepoint
registration of gingival inflammation status before and 1 month after intervention

Method of measurement
examination and registration of condition

Intervention groups

1

Description
Educational intervention is done in the form of counseling and motivational interview with the patient in the presence of his parents. First, the researcher states the purpose of the consultation and provides information about the causes of gingivitis, how dental plaque forms, and the effect of sugary and acidic foods on caries. Then we talk about the reasons that may affect dental hygiene behaviors. For example, the patient is asked not to delay the time of brushing so that fatigue does not prevent the control of plaque, or be sure to brush each time after the main meals. Apply fluoridated toothpaste, lasting at least two minutes at a time, and after brushing try to simply spit out the water and preferably not rinse the mouth with water. It is recommended that parents monitor their children's brushing. It also explains how oral health control affects the freshness of breathing and improves social relationships and acceptance of others. It is also noted that in the new conditions created by orthodontics in the mouth, the need for increased plaque control should be thoroughly cleaned. The patient is asked to comment and ask questions, positive behaviors are encouraged, identification problems and possible solutions are provided. Then the child is taught to brush and floss first on the model and then inside the mouth. During this stage, the patient follows the steps with the mirror he has, and in the next stage, the patient must repeat what he has learned in front of the mirror. A brochure containing information on how to brush and

floss properly is also provided at the end. To motivate and be more effective, the patient is called once a week during the intervention, which is about a month.

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Dentistry, Tehran University of Medical Sciences
Full name of responsible person
Mahdia Gholami
Street address
First Floor, Department of Oral Health and Social Dentistry, School of Dentistry, beside Atomic Energy, North Kargar End, Enghelab Square.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice President for Research
Street address
Enghelab Square, North Kargar End, Atomic Energy, School of Dentistry, First Floor, Department of Oral Health and Social Dentistry
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Email
dentistry@tums.ac.ir
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

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

Tehran

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Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shima Ziari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahdia Gholami

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

Street address

dental school of Tehran University of Medical Sciences, next to Atomic energy, North Krgar st

City**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

Still under investigation.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available