Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 to16 years, patients participated in the study voluntarily,signing Consent by parents Conditions of absence:had a physical disability,had a systemic or underlying disease witch 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
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Iran (Islamic Republic of)
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+98 21 8889 1058
Email address
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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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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

40

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
Shima Ziari

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
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Associate Professor

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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Shima Ziari

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
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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
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