Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of active reminder of oral health education during fixed orthodontic treatment on plaque index and bleeding on probing

Protocol summary

Study aim

The effect of active reminder of oral health education during fixed orthodontic treatment on plaque index and bleeding on probing

Design

Analytical study of clinical trial with control group.double bilnd with parallel groups on 40 patients.The table of random numbers will be used for randomization.

Settings and conduct

Patient applying for fixed orthodontic treatment who will refer to dental clinic affiliated to the Shahid Sadoughi University of Medical Scinces, Yazd, will be randomly assigned to two groups without knowing about the groupnig.The first group just receives the hygiene education at the beginning of the treatment .The intervention group in addition primary hygiene education, will receives the reminder text messages .At the begining ,the fourth and the twelfth weeks after the start of the study ,Plaque index and the bleeding on probing will be measured .The examiner and the analyzor dont know the groupng of the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 12-25 years old permanent teeth system without trauma history accss to mobile phone needing to upper jaw fixed orthodontic treatment Exclusion criteria: systemic disease antibiotic therapy periodontal disease smoking electric tooth brush

Intervention groups

Patient will be divided into two groups.The first group will be considered as control and will only receive the same initial training before starting the treatment.In addition to the initial training the second group will receive oral hygiene training daily in first month and twice a week in the second and third months.

Main outcome variables

Plaque index Bleeding on probing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230304057614N1**
Registration date: **2023-05-03, 1402/02/13**
Registration timing: **prospective**

Last update: **2023-05-03, 1402/02/13**
Update count: **0**

Registration date

2023-05-03, 1402/02/13

Registrant information

Name
Neda Joshan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3621 2222
Email address
n.joshan@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-20, 1402/03/30

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of active reminder of oral health education during fixed orthodontic treatment on plaque index and bleeding on probing

Public title
The effect of active reminder of health education on hygiene indexes during fixed orthodontic treatment
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 12-25 Permanent teeth system Without trauma history Available phone Needing to upper jaw fixed orthodontic treatment
Exclusion criteria:
Systemic disease Smoking Antibiotic therapy Electric tooth brush
Age
From **12 years** old to **25 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is simple and the unit of randomization is the individual. Using the table of random numbers, patients will be randomly placed in two groups: the group without reminders and the group with reminders. Even numbers for the group without reminders and odd numbers for the group a reminder Random allocation is done by the researcher, and the clinical caregiver and the analyst are not aware of the allocation of patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
Random allocation is done by the researcher, and the clinical caregiver and the analyst are not aware of the allocation of patients. An impartial examiner who is a dental intern and does not know the grouping of the participants, collect the data and record the information.The analyzor does not know about the patient grouping too.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee in Biomedical Research
Street address
Block NO A-central headquarters of the ministry of health-Sima Iran Street-Quds
City
Tehran
Province
Tehran
Postal code
8915173160
Approval date
2020-04-20, 1399/02/01
Ethics committee reference number
IR.SSU.REC.1399.015

Health conditions studied

1

Description of health condition studied
Plaque index and bleeding on probing
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plaque index
Timepoint
First of syudy-fourth week from the beginning of the study-the twelfth week from the beginning of the study
Method of measurement
Observation by prob and dental mirror

2

Description
Bleeding on probing
Timepoint
First of syudy-fourth week from the beginning of the study-the twelfth week from the beginning of the study
Method of measurement
Observation by prob and dental mirror

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After oral health education in the

begining of the treatment by dentist, active reminding of oral health education by SMS in the beginning of study then daily in first month after that two times a week in second and third months will be sent .The content of the SMS is a reminder to do oral and dental hygiene by using a manual toothbrush and dental floss in accordance with standard prophylactic principle.

Category

N/A

2

Description

Intervention group: this group receives oral and dental hygiene recommendations from the dentist at the beginning of the treatment and they do not receive reminder messages

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

dental clinic affiliated to Shahid Sadoughi University of Medical Sciences .YAZD

Full name of responsible person

Neda Joshan

Street address

Imam Reza Squre-dahe Fajr blvd

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3625 6975

Fax

+98 35 3625 6975

Email

Neda.joshan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Neda Joshan

Street address

Imam Reza Squre-Dahe Fajr blvd

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3621 2222

Fax

+98 35 3621 2222

Email

Neda.joshan@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

50

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

Yazd University of Medical Sciences

Full name of responsible person

Reyhanehalsadat Jafari

Position

Postgraduated Student, Department Of Oral and Maxillifacial Radiology School of Dentistry, Shahid Sa

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Imam Reza Squre -Dahe Fajr blvd

City

Yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3621 2222

Fax

+98 35 3621 2222

Email

jafari_rs@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Reyhanehalsadat Jafari

Position
Postgraduated Student, Department of Oral and Maxillofacial Radiology School of Dentistry, Shahid Sa
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Imam Reza Squre - Dahe Fajr blvd
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3621 2222
Fax
+98 35 3621 2222
Email
jafari_rs@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Reyhanehalsadat Jafari
Position
Postgraduated Student, Department of Oral and Maxillofacial Radiology School of Dentistry, Shahid Sa
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Imam Reza Square_Dahe Fajr blvd
City
Yazd
Province
Yazd
Postal code
8914881167
Phone
+98 35 3621 2222
Fax
Email
jafari_rs@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available