

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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 blind 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 Sciences, Yazd, will be randomly assigned to two groups without knowing about the group. The first group just receives the hygiene education at the beginning of the treatment. The intervention group in addition primary hygiene education, will receive the reminder text messages. At the beginning, 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 analyzer don't know the group of the patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 12-25 years old permanent teeth system without trauma history access 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 analyzer 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 study-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 study-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 Squire-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 Squire-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 Squire -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
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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

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

Yazd University of Medical Sciences

Full name of responsible person

Reyhanehalsadat Jafari

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