

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

A clinical trial to compare the effectiveness of the health education by assistant with social media on oral hygiene in fixed orthodontic patients

Protocol summary

Study aim

To compare the effectiveness of the health education by assistant with social media on oral hygiene in fixed orthodontic patients

Design

This randomized and single-blind clinical trial with parallel and control groups will be conducted on 60 patients who will be randomly selected using the blocks.

Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive health education by social media and control by assistant for oral hygiene. The person responsible for data collection is blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No having tooth decay; no having soft tissue diseases; having fixed orthodontic appliances; having cell phone for install applications and learning program. Exclusion criteria: Having systemic diseases.

Intervention groups

The intervention group will receive health education via social media that is available to the patient (how to brush their teeth and using orthodontic flossers). The control group will receive health education via assistant on the dental model (how to brush their teeth and using orthodontic flossers).

Main outcome variables

Evaluation and comparison of the orthodontic plaque index and gingival index (discolored gums, inflammation and change in texture in the gums) in control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200609047705N2**

Registration date: **2021-07-13, 1400/04/22**

Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**

Update count: **0**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

Homan Shafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

shafaeeh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of the health education by assistant with social media on oral hygiene in fixed orthodontic patients

Public title

The effectiveness of health education on oral hygiene in fixed orthodontic patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

No having tooth decay No having soft tissue diseases
Having fixed orthodontic appliances Having cell phone for install applications and learning program

Exclusion criteria:

Having systemic diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use the restricted randomization method of block randomization. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive health education by social media and control by assistant for oral hygiene. The person responsible for data collection is blind to group allocation and the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2020-12-16, 1399/09/26

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1399.118

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

Orthodontic

ICD-10 code

Z46.4

ICD-10 code description

Encounter for fitting and adjustment of orthodontic device

Primary outcomes**1****Description**

Orthodontic plaque index

Timepoint

Before and one month after intervention

Method of measurement

Staining the teeth or surfaces with a plaque-disclosing solution such as erythrosine

2**Description**

Gingival index (discolored gums, inflammation and change in texture in the gums)

Timepoint

Before and one month after intervention

Method of measurement

During the examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive health education via social media that is available to the patient (how to brush their teeth and using orthodontic flossers).

Category

Prevention

2

Description

Control group: The control group will receive health education via assistant on the dental model (how to brush their teeth and using orthodontic flossers).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

Full name of responsible person

Homan Shafaei

Street address

Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd

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9177948959

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shafaeeh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Homan Shafaei

Position

Orthodontic

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific

inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The research data obtained from the main outcomes of the study can be shared freely as 'open data'.

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

Under which criteria data/document could be used

The research data is exclusively accessible to the researchers working at universities and centers for scientific research.

From where data/document is obtainable

Homan Shafaei provides the data analysis to the applicants via email: shafaeeh@mums.ac.ir

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

Applicants can send emails to him and receive a response within a week.

Comments