

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of effectiveness of smartphone reminder application on oral hygiene compliance in patients with fixed orthodontic appliance: a randomized clinical trial

Protocol summary

Study aim

Determining the Effect of Using the Smartphone's Reminder App in Patients' Oral hygiene compliance with Orthodontics' fixed appliances

Design

In this study, 120 patients in two groups of control and intervention during a 3-month period will be studied. For blindness In this study, a clinician who measures the plaque index and gingival index of patients will not be aware of the presence of each patient in the control or intervention group.

Settings and conduct

Participants in this study will be 120 orthodontic patients between the ages of 25 and 15 years old whom referred to Hamadan Dental university and Dental Clinic. Patients will be examined during the three month period, and the initial examination will begin after signing of the testimonial by the patients or their parents . Patients' plaque index and gingival index will measured in baseline (T0) after 4 weeks (T1), 8 weeks (T2) and after 12 weeks (T3). at the beginning of the study, the Brushdj application is given to the intervention group. In this study, the clinician that measures the patients' plaque and gingival index will be blind.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1-girls and boys between 15-25 years old 2-patients that have their orthodontic appliances at least 12 weeks after starting the study 3-do not remove their appliance before finishing the study 4-do not have mental and physical disability 5-do not have enamel or dentin dysplasia or craniofacial abnormalities 6-patients smart phone with android $\geq$ 4.0.3 or IOS $\geq$ 9 exclusion criteria: 1-Patients who use drugs that are effective on the plaque accumulation such as antibiotics or antibacterial mouth rinses. 2- Individuals with any type of mental disorder whom has been diagnosed by psychiatrist .

Intervention groups

control and intervention group

Main outcome variables

Improvement of oral hygiene compliance in fixed orthodontic ptients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190106042253N1**

Registration date: **2019-02-03, 1397/11/14**

Registration timing: **prospective**

Last update: **2019-02-03, 1397/11/14**

Update count: **0**

Registration date

2019-02-03, 1397/11/14

Registrant information

Name

Homa Farhadifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3835 4250

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effectiveness of smartphone reminder application on oral hygiene compliance in patients with fixed orthodontic appliance: a randomized clinical trial

Public title

Evaluation of effectiveness of smartphone application on oral hygiene in orthodontic patients

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

girls and boys between 16-20 years old patients that have their orthodontic appliances at least 12 weeks after starting the study do not remove their appliance before finishing the study do not have mental and physical disability do not have enamel or dentin dysplasia or craniofacial abnormalities patients smart phone with android $\geq$ 4.0.3 or IOS $\geq$ 9

Exclusion criteria:

1-Patients who use drugs that are effective on the plaque accumulation such as antibiotics or antibacterial mouth rinses. 2- Individuals with any type of mental disorder whom has been diagnosed by psychiatrist .

AgeFrom **15 years** old to **25 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample sizeTarget sample size: **120****Randomization (investigator's opinion)**

Randomized

Randomization description

simple randomization with blocking

Blinding (investigator's opinion)

Single blinded

Blinding description

for blinding in this study, the clinician that evaluating plaque and gingival index dose not know that patient is in control or study group and patient dose not speak about his or her group with each other or with clinician

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Hamadan university of medical sciences

Street address

Shahid fahmide avenue

City

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Postal code

6517838678

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number

IR.UMSHA.REC.1397.725

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

oral hygiene compliance in fixed orthodontic patients

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

plaque index

Timepoint

in the baseline(before intervention,4,8 and 12 weeks after beginning of the study

Method of measurement

dental plaque disclosing agents

2**Description**

gingival index

Timepoint

in the baseline(before intervention,4,8 and 12 weeks after beginning of the study

Method of measurement

periodontal prob

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

Frequency of brushing per day

Timepoint

from the beginning of intervention till 90 days later

Method of measurement

questionnaire

2**Description**

brushing duration per day

Timepoint

from the beginning of intervention till 90 days later

Method of measurement

questionnaire

Intervention groups**1****Description**

Control group: Individuals who are in the control group are provided with educational brochures on how to brush correctly. They also complete the form for 3 months, which includes information on the number and duration of brushing and the frequency of use of mouthwashes.

Category

Behavior

2**Description**

Intervention group: Individuals in this group receive the Brushdj app in addition to the brochures and the form that the control group also receive. These people use reminders of the app to not forget the brushing time. Also, the 2-minute timer of this app is used to ensure that the brush is used for a long time.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental faculty of Hamadan university

Full name of responsible person

Homa Farhadifard

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2**Recruitment center****Name of recruitment center**

Hamadan university dental clinic

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Homa Farhadifard
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All collected data would be shared without patients name or identification data

When the data will become available and for how long

starting in 2022

To whom data/document is available

Academic institution

Under which criteria data/document could be used

The data can be used in larger, multi center studies

From where data/document is obtainable

Researchers can assess data by emailing at
homa.far1989@gmail.com

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

After emailing the request for data, the data would be sent in 1 week to the researcher.

Comments