

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effect of Text Message Reminders on Oral Hygiene Promotion During Removable Orthodontic Treatment

Protocol summary

Study aim

This study aimed to assess the effect of weekly text message reminders to parents or legal guardians of children under removable orthodontic treatment on their oral hygiene.

Design

In this 2-arm parallel randomized controlled trial, 50 participants were randomly allocated to two groups. Randomization was done with Minimization method by Minim soft ware

Settings and conduct

This study was done at Department of Orthodontic, School of Dentistry, Shiraz Branch, Azad University. In the first phase (T1), message reminders group received video and text messages containing information about the significance of oral hygiene twice a week for 4 weeks. In the second phase (T2) and third phase (T3), patients received reminder messages once a week for 2 months and once a week for 3 months, respectively. Control group received no message. Plaque index and gingival index were recorded at baseline (T0) and one (T1), three (T2) and six (T3) months after the first day of treatment by the same blinded examiner who did not have any information about participant's division in the two groups.

Participants/Inclusion and exclusion criteria

8-12 years old children whose treatment plan included the use of a removable orthodontic appliance made of auto-polymerizing acrylic resin with a midline screw and had a minimum treatment duration of six months were selected in this study. Patients who did not have daily access to Internet by their own smartphone or their parent, or had specific nutritional regimens, systemic diseases, syndromic anomalies such as cleft lip or palate and physical or mental disability were excluded.

Intervention groups

Patients were divided randomly into two groups of messaging and control. The patients in messaging group received text messages and videos as oral hygiene

reminder while the control group did not receive any message.

Main outcome variables

Plaque and Gingival index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041092N2**

Registration date: **2020-07-25, 1399/05/04**

Registration timing: **retrospective**

Last update: **2020-07-25, 1399/05/04**

Update count: **0**

Registration date

2020-07-25, 1399/05/04

Registrant information

Name

Tahereh Baherimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3649 1516

Email address

t_baheri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-20, 1398/01/31

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

2019-04-20, 1398/01/31

Actual recruitment end date

2019-07-22, 1398/04/31

Trial completion date

2020-02-11, 1398/11/22

Scientific title

Effect of Text Message Reminders on Oral Hygiene Promotion During Removable Orthodontic Treatment

Public title

Effect of Reminders on Oral Hygiene Promotion

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being orthodontic patients for 6 months at least Having removable orthodontic appliance made of auto-polymerizing acrylic resin with a midline screw

Exclusion criteria:

No daily access to Internet by smartphone or parents were not at home at the time of sending text messages due to their occupational schedule Specific nutritional regimens Systemic diseases Syndromic anomalies such as cleft lip or palate and physical or mental disability.

Age

From **8 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomized according to the minimization method proposed by Pandis. Minimization is a method of randomization used to ensure the balance of important prognostic factors among the groups and does not have the disadvantages of other randomization methods. List of randomization was not prepared in this method before the beginning of study; instead, it was prepared in the process of selection of participants. It is a dynamic method of randomization. In the Minimization method, the first participant randomly entered into one of the groups and the next participant is entered into a group that has a lower predetermined factor in that group. for example, if the first participant, who is an 8-year-old boy, joins the intervention group, the second participant who is a 10-year-old boy, will enter the to control group, by this way balance can be obtained in one of the predetermined factor "the sexuality" at least. Minimization can be easily performed using software (Minim). However, the important point before using this software is to determine the important prognostic factors between groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

1. Examiner clinician
2. Person performed the data entry
3. Statistician were unaware of patients group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kazerun Branch, Islamic Azad University, Iran.

Street address

5 km of Kazerun-Bushehr road

City

Kazerun

Province

Fars

Postal code

7319846451

Approval date

2020-06-19, 1399/03/30

Ethics committee reference number

IR.IAU.KAU.REC.1399.008

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

The normal gingiva may range in color from light coral pink to heavily pigmented. It is normally stippled in appearance (resembling an orange peel). The makeup of the gingival tissue varies according to its location and function. There are two types of gingiva and several important anatomic regions. Free gingiva - This tissue is not attached and forms a collar around the tooth. The trough around the tooth is called the sulcus and its depth is normally 1-3 mm. It is lined with sulcular epithelium and attached to the tooth at its base by the epithelial attachment. Gingival margin - The border region of the gingiva that touches the tooth. Interdental papillae - The region of gingival tissue that fills the space between adjacent teeth. In a healthy mouth this is usually knife-edged and fills the interdental space. Muco-gingival junction - The scalloped line that divides the attached gingiva from the alveolar mucosa.

ICD-10 code

K05

ICD-10 code description

Gingivitis and periodontal diseases

Primary outcomes

1

Description

Gingival inflammation

Timepoint

After one, three, and six month

Method of measurement

By using silness loe index

2

Description

Periodontal pocket depth

Timepoint

After one, three, and six month

Method of measurement

By using periodontal probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first phase (T1), the messaging group received video and text messages containing information about the significance of oral hygiene twice a week for 4 weeks. Time of sending the text messages was determined such that both the parents and patients were at home. The time interval between lunch and dinner was often chosen for most patients. For the rest of the patients, a convenient time was arranged following discussion with the parents. In the second phase (T2), patients received a message reminder for oral hygiene and educational videos once a week for 2 months. In the third phase (T3), message reminders were sent to the messaging group once a week for 3 months. Plaque index (PI), gingival index (GI) were recorded at baseline (T0) and one (T1), three (T2) and six (T3) months after the first day of treatment by the same blinded examiner who did not have any information about participant's division in the two groups.

Category

Rehabilitation

2

Description

Control group: They received no video and text messages containing information about the significance of oral hygiene during study. Plaque index (PI), gingival index (GI) were recorded at baseline (T0) and one (T1), three (T2) and six (T3) months after the first day of treatment by the same blinded examiner who did not have any information about participant's division in the two groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Branch, Islamic Azad University

Full name of responsible person

Tahereh Baheri Moghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz Branch, Islamic Azad University

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

Shiraz Branch, Islamic Azad University

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

Shiraz Branch, Islamic Azad University

Full name of responsible person

Tahereh Baheri Moghadam

Position

Assistant Professor

Latest degree

Specialist

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Orthodontics

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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

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

Effect Message Reminders on Oral Hygiene Promotion

During Removable Orthodontic Treatment

When the data will become available and for how long

Data is available after the article is published

To whom data/document is available

For all those who have an official request.

Under which criteria data/document could be used

None of the patients' names should be mentioned anywhere

From where data/document is obtainable

It is available through the ,corresponding for information.

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

Official request from the University's Vice Chancellor for Research

Comments