

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparative evaluation of virtual versus verbal oral hygiene instructions on periodontal indices in patients with fixed orthodontic appliances

Protocol summary

Study aim

Effectiveness of virtual versus verbal oral hygiene instructions on periodontal indices in patients with fixed orthodontic appliances

Design

This research is a single-blind, parallel, randomized prospective clinical trial. Study sample is determined through repeated measures design. Considering 4 repetitions, correlation of 0.50, 95% confidence interval and significance level of 0.05, we use a variance of 0.020 from a previous studies, sample size in each group was calculated to be at least 23 patients. R package for randomization of clinical trials will be used. This clinical trial is categorized as phase 3.

Settings and conduct

Convenient sampling will be used from those referring to an assigned orthodontic clinic. Patients are randomly assigned into two groups. Clinical examiner who measures and records the indices is totally blind to the study protocol.

Participants/Inclusion and exclusion criteria

Patients are young adults who are diagnosed to be treated with fixed orthodontic appliances. Educated, non-smokers, having a smart phone with internet access is the primary needs to be included in the study. Having diabetes, immune diseases, taking medication with periodontal side effects, lactating or pregnant women are excluded.

Intervention groups

Participants will be divided in two groups. All the participants will receive a standard oral hygiene instruction in-person at baseline upon starting the treatment. Afterwards, one group will receive oral hygiene instruction recalls in person once a month during routine orthodontic treatment while the other group receive virtual recalls every two weeks for the duration of the study.

Main outcome variables

Primary outcomes include: Dental plaque index, gingival

bleeding index, and index of gingival inflammation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080824001081N9**

Registration date: **2019-12-23, 1398/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-23, 1398/10/02**

Update count: **0**

Registration date

2019-12-23, 1398/10/02

Registrant information

Name

Golpar Radafshar

Name of organization / entity

Guilan University of Medical Sciences, School of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 13 1323 0775

Email address

golshad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative evaluation of virtual versus verbal oral hygiene instructions on periodontal indices in patients with fixed orthodontic appliances

Public title
Effectiveness of virtual oral hygiene instruction on periodontal health in fixed orthodontic patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients in need for fixed orthodontic treatment including first molar teeth. Ability to write and read Having a smart phone with daily access to the internet Agreement upon signing an informed consent
Exclusion criteria:
 Taking any anti-inflammatory and/or antibiotic medication during past three months Receiving any periodontal treatment during past 6 months Diabetes Cigarette smoking Inflammatory joint diseases Pregnancy and/or lactation Taking immunosuppressive medication during past 3 months Mouth breathing with inadequate lip closure Taking medications with periodontal side effects such as, Nifedipine, Cyclosporine, Phenytoin, Dilantin Any nutritional disorders

Age
From **15 years** old to **30 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomize R package for clinical trials.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this research, the clinical examiner who evaluates and records the periodontal indices at baseline, 1 and 3 months post intervention is blinded to the case and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Dental Faculty of Guilan University of Medical Sciences, Fuman-Saravan Highway

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2019-12-05, 1398/09/14

Ethics committee reference number

IR.GUMS.REC.1398.418

Health conditions studied

1

Description of health condition studied

Chronic plaque-induced gingival inflammation

ICD-10 code

K05.10

ICD-10 code description

ژنژیویت مزمن مارجینال ساده

2

Description of health condition studied

dental plaque

ICD-10 code

K03.6

ICD-10 code description

Deposits [accretions] on teeth

Primary outcomes

1

Description

plaque index

Timepoint

Baseline, one and three months post-intervention

Method of measurement

Plaque index, Silness and Loe

2

Description

Gingival inflammation

Timepoint

Baseline, one and three months post-intervention

Method of measurement

Modified gingival index, Loe and Silness

3

Description

Gingival bleeding index

Timepoint

Baseline, one and three months post-intervention

Method of measurement

Gingival bleeding index, Lenox and Kopczyk

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients receive standard oral hygiene instructions in the clinic which include Modified Bass brushing technique, dental flossing and use of interdental brushes. Instructions will be given to the patients at baseline (before orthodontic treatment), and repeated every month for 3 months after initiation of orthodontic treatment.

Category

Prevention

2

Description

Intervention group: Patients receive standard oral hygiene instructions in the clinic and in-person only at baseline (before starting orthodontic treatment) which include Modified Bass brushing technique, dental flossing and use of interdental brushes. After initiation of orthodontic treatment, instructions will be given to the patients every two weeks for the following three months through videos using the WhatsApp installed on the patients' smart phones.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of orthodontics, Faculty of Dentistry,
Guilan University of Medical Sciences

Full name of responsible person

Parvaneh Abbaspour Mozhdehi

Street address

Gilan University of Medical Sciences, Fuman-Saravan
highway

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3348 6406

Fax

+98 13 3348 6423

Email

dental@gums.ac.ir

Web page address

<http://www.gums.ac.ir/dental>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipoor

Street address

6th floor, central building of the Gilan University of
Medical Sciences, opposite Azodi stadium, Namjoo
Street

City

Rasht

Province

Guilan

Postal code

41446-56513

Phone

+98 13 3322 9599

Fax

+98 13 3332 2444

Email

research@gums.ac.ir

Web page address

<http://www.gums.ac.ir/research>

Grant name

Grant code / Reference number

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

No

Title of funding source

researchers

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr, Golpar Radafshar

Position

Associate professor of Periodontology, Department of Periodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Fuman-Lakan Highway

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3348 6406

Fax

+98 13 3348 6423

Email

golishad@gmail.com

Web page address

<http://www.gums.ac.ir/dental>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Golpar Radafshar

Position

Associate Professor of Periodontology, Department of Periodontics

Latest degree

Specialist

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Fax

+98 13 3348 6423

Email

golshad@gums.ac.ir

Web page address

<http://www.gums.ac.ir/dental>

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Parvaneh Abbaspoor Mozhdehi

Position

Dental student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Fuman-Saravan Highway

City

Rasht

Province

Guilan

Postal code

41941-73774

Phone

+98 13 3348 6406

Email

parvanehmojdehi22@gmail.com

Web page address

<http://www.gums.ac.ir/dental/Default.aspx?tabid=902>

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants do not consent that their data get published.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Since we intend to publish an article based on the present research, the only available data is through the potential article.

When the data will become available and for how long

Within the next 6-8 months the article will get ready for submission and an exact date of publication is not predictable since it depends on the assigned journal policy,

To whom data/document is available

Researchers intend to publish the article in an open access journal so all the stakeholders and interested professionals will be able to access to the content.

Under which criteria data/document could be used

This research will be published in line with the international and national goal for improving dental and periodontal hygiene instruction among young adults.

From where data/document is obtainable

Searching the article key words in any search engine

would guide the interested people to the article.

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

No particular process will not be necessary.

Comments