

The effective brush for patients with orthodontic appliances

Submission date 03/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/04/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/06/2023	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The use of manual toothbrushes plays a fundamental role in oral hygiene. However, controlling dental plaque accumulation for preventing gingivitis (gum disease), periodontitis (gum infection), and tooth decay is highly influenced by several individual and material-based factors. Among the individual factors, the presence of fixed orthodontic appliances on tooth surfaces such as brackets and bands creates difficulties in maintaining good oral hygiene, leading to the buildup of plaque. Although there is considerable evidence showing the superiority of powered, particularly oscillating rotating brushes when compared to manual brushes in patients with fixed orthodontic appliances, there is limited evidence regarding the effectiveness of advanced bristle designs (multilevel, criss-cross) of the manual toothbrush alone in removing plaque on patients undergoing orthodontic treatment, except for a few that have compared manual brushes with orthodontic brushes with conflicting reports of effectiveness. The aim of this study is to compare the effect of three types of manual toothbrushes (cross-action, flat trim and orthodontic brush) on plaque removal in patients with fixed orthodontic appliances.

Who can participate?

Patients aged 18 to 25 years wearing fixed orthodontic appliances attending the Orthodontic Clinic at the Dental Centre, Ministry of National Guard - Health Affairs

What does the study involve?

Participants will be randomly divided into three treatment sequences (ABC, BCA, CAB):

A: Toothbrush with flat bristles

B: Toothbrush with zigzag bristles

C: Toothbrush with crisscross bristles

Participants attend three clinic visits 1 week apart and at each visit they carry out a single 2-minute brushing exercise with the allocated brush. The clinician will check the participant's plaque before and after the brushing exercise.

What are the possible benefits and risks of participating?

The risks and inconvenience will be very minimal limited to participants sparing some of their valuable time. There will be no direct benefit from participation in this study but it may help in the advancement of knowledge and health science progress.

Where is the study run from?

King Saud bin Abdulaziz University for Health Sciences (KSAU-HS) (Saudi Arabia)

When is the study starting and how long is it expected to run for?

November 2019 to May 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Fathima Fazrina Farook

fazrinaf@ksau-hs.edu.sa

Contact information

Type(s)

Principal investigator

Contact name

Dr Fathima Fazrina Farook

ORCID ID

<https://orcid.org/0000-0002-2257-2662>

Contact details

College of Dentistry

King Saud bin Abdulaziz University for Health Sciences (KSAU-HS)

Riyadh

Saudi Arabia

11426

+966 (0)531051380

fazrinaf@ksau-hs.edu.sa

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Efficacy of manual toothbrushes in patients with fixed orthodontic appliances: a randomized clinical trial

Study objectives

To clinically compare the effect of three types of manual toothbrushes (cross-action, flat trim, and orthodontic brush) on plaque removal when the modified Bass method of brushing is used in patients with fixed orthodontic appliances.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 11/12/2019, the King Abdullah International Medical Research Center Institutional Review Board (Ali Al Arini, Ar Rimayah, Riyadh 11481, Saudi Arabia; +966 (0)11 429 4444; irb@ngha.med.sa), ref: RC19/432/R

Study design

Randomized cross-over controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Plaque removal in patients with fixed orthodontic appliances

Interventions

The study subjects (n = 30) will be randomly divided into three treatment sequences using a computer-generated randomisation method (ABC, BCA, CAB) with approximately 10 subjects in each treatment sequence:

Group A: Toothbrush with flat bristles

Group B: Toothbrush with zigzag bristles

Group C: Toothbrush with crisscross bristles

Participants attend three clinic visits 1 week apart and at each visit they carry out a single 2-minute brushing exercise with the allocated brush. The clinician will check the plaque before and after the brushing exercise.

Intervention Type

Device

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

-

Primary outcome(s)

Plaque scored using the Turesky Modified Quigley-Hein Plaque Index at baseline and following a single brushing exercise

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

01/05/2022

Eligibility**Key inclusion criteria**

1. Aged 18 to 25 years
2. In good general and oral health
3. Wearing fully bonded fixed orthodontic appliances
4. Good hand dexterity
5. Without any disabilities
6. A minimum of 25 natural teeth with facial and lingual scorable surfaces without any oral lesions
7. Periodontal pockets of 3 mm or loss of attachment/recession of 2 mm

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

34

Key exclusion criteria

1. Evidence of mucogingival problems
2. Smoking
3. Pregnancy
4. Five or more carious lesions requiring restorative treatment
5. Heavy restorations
6. Wearing fixed or removable prostheses
7. Participation in any other elective dental procedure, including prophylaxis, during the study period
8. Evidence of any disease or condition that may interfere with the study procedures

Date of first enrolment

01/11/2020

Date of final enrolment

01/06/2021

Locations

Countries of recruitment

Saudi Arabia

Study participating centre

King Saud bin Abdul Aziz University for Health Sciences

Arrimayah

Riyadh

Saudi Arabia

14611

Sponsor information

Organisation

King Abdullah International Medical Research Center

ROR

<https://ror.org/009p8zv69>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Dr Fathima Fazrina Farook (fazrinaf@ksau-hs.edu.sa) can be contacted for access to the datasets. Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices), will be shared starting 3 months and ending 5 years following article publication for individual participant data meta-analysis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/05/2023	12/06/2023	Yes	No