

# The effective brush for patients with orthodontic appliances

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

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## Contact information

### Type(s)

Principal Investigator

### Contact name

Dr Fathima Fazrina Farook

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

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

### **Secondary study design**

Randomised cross over trial

### **Study setting(s)**

Home

### **Study type(s)**

Prevention

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **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 measure**

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

**Secondary outcome measures**

There are no secondary outcome measures

**Overall study start date**

01/11/2019

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**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

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**Sponsor information****Organisation**

King Abdullah International Medical Research Center

**Sponsor details**

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**Sponsor type**

Research organisation

**Website**

<http://kaimrc.med.sa/>

**ROR**

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

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/10/2022

**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?
<a href="#">Results article</a>		23/05/2023	12/06/2023	Yes	No