ISRCTN14766887 https://doi.org/10.1186/ISRCTN14766887

The effective brush for patients with orthodontic appliances

Submission date	Recruitment status	[_] Prospectively registered
03/04/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/04/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2023	Oral Health	

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 shwoing 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

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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
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Sponsor information

Organisation
King Abdullah International Medical Research Center

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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?
Results article		23/05/2023	12/06/2023	Yes	No