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Manual versus powered tooth brushing in orthodontic patients

Submission date
22/12/2013

Recruitment status
No longer recruiting

Registration date
26/06/2014

Overall study status
Completed

Last Edited
15/09/2023

Condition category
Oral Health

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Orthodontic treatment is a type of dentist treatment which aims to improve the appearance, position and function of teeth that are crooked or in an abnormal position in the mouth. One such treatment is fitting an orthodontic brace for a set period of time to correct the positioning of the teeth or to straighten them. Wearing orthodontic braces, however, can make maintaining good oral hygiene a challenge, with the wires and attachments making it difficult for the toothbrush to gain access to the teeth. This can result in the build-up of plague and debris, which, in turn, can lead to gingivitis (gum inflammation and bleeding), and damage to the teeth such as decalcification around brace attachments. It is therefore important to measure the amount of plague in these more difficult to access areas. It has been suggested that powered toothbrushes are more effective in preventing gingivitis than manual toothbrushes. Such an advantage would be of particular interest to people who wear orthodontic braces. However there is insufficient evidence to support the comparative effectiveness of powered toothbrushes in reducing gingivitis in these patients. Here, we aim to address this by comparing the levels of plaque control, gingival health and enamel decalcification in patients wearing braces using either a powered toothbrush or a manual one.

Who can participate?
Patients aged 12-18 years who require fixed braces for their teeth.

What does the study involve?
Participants will be randomly allocated to one of two tooth brushing groups (a control and an intervention group). Plaque score (a measure of how much plaque is on the teeth) and gum health measurements (assessing inflammation, pockets around the teeth and bleeding) for each patient are taken before the start of treatment. Both groups are treated with fixed orthodontic braces. All patients in the control group are given the same type of manual toothbrush and all patients in the intervention group are given the same type of powered toothbrush. Patients are shown how to keep their teeth clean using their allocated toothbrush. All patients have brush for two minutes each morning and evening. No other oral hygiene devices, mouth rinses or dentifrices can be used. All subjects have their plaque and gum health measured at 1, 6 and 12 months with the final scoring being at the debond (removal of braces) appointment. Enamel decalcification measurements are also taken at the start and at debond appointments.

What are the possible benefits and risks of participating?
Risks associated with orthodontic treatment and include decay or decalcification due to decreased oral hygiene or increased sugar intake, gum disease due to decreased oral hygiene, root shortening (resorption) and relapse. Tooth brushing either manual or electric form part of a persons' normal daily oral hygiene regime and the risks are minimal.

Where is the study run from?
The Orthodontic Department, Barts and The London School of Medicine and Dentistry (UK)

When is the study starting and how long is it expected to run for?
February 2014 to September 2020

Who is funding the study?
London Alpha Omega Charitable Trust & Barts Health Orthodontic department (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4/009127 QM

Study information

Scientific Title
Manual versus powered tooth brushing in orthodontic patients: a randomised controlled trial

Study objectives
1. There is a difference in the levels of plaque control, gum health and risk of damage to tooth enamel (decalcification) when comparing powered toothbrushes with manual toothbrushes in patients with braces (orthodontic patients).
2. A patient's short term plaque control and gingival health can predict the risk of damage to their tooth enamel at the end of treatment.

The null hypotheses are:
1. There is no significant difference in plaque control levels, gum health and damage to tooth enamel rates in patients using powered tooth brushing in comparison to those using manual tooth brushes in the short term or long term.
2. A patients short term plaque control and gum health cannot predict tooth enamel damage risk at the end of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bloomsbury NRES Committee London, 27/02/2014, ref: 14/LO/0003

Study design
Prospective randomised single blinded trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Best type of toothbrush for orthodontic patients

Interventions
Patients are randomised to two groups: intervention and control groups
The intervention group will be instructed to use a powered toothbrush, twice a day for the whole period they are in braces, whereas the control group will use a manual toothbrush, twice a

day for the whole period they are in braces.
Participants in both groups are followed up 1 month after fixed appliance placement (T1), 6 months (T2), 12 months (T3) months and at debond (T4).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To compare the means of the two groups with respect to the plaque and gingivitis indices at 1, 6, 12 months and at the debond appointment. Levels of decalcification will also be measured at the debond appointment

Secondary outcome measures
Whether the results at 1 month can serve as a predictor of how a patients plaque control and gum health will be like, as well as be a forecaster of enamel decalcification at the end of treatment.

Overall study start date
03/02/2014

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Patients aged 12-18 years at start of treatment
2. Upper and lower preadjusted Edgewise appliances
3. Brushing at least once a day
4. Good general health
5. Non-smokers

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
92

Total final enrolment
92

Key exclusion criteria
1. Learning difficulties or special needs
2. Poor periodontal health (including the presence of supra and subgingival calculus or periodontal pocketing as determined by BPE codes 2, 3 or 4)
3. Oral prophylaxis in previous 4 weeks
4. Use of antibacterial mouth rinses

Date of first enrolment
10/07/2014

Date of final enrolment
20/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Barts and The London School of Medicine and Dentistry
London
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Sponsor information

Organisation
Queen Mary, University of London (UK)

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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
London Alpha Omega Charitable Trust (UK)

Funder Name
Barts Health NHS Trust (UK) - Orthodontic department

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		14/09/2023	15/09/2023	Yes	No