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Effectiveness of an audiovisual method for oral hygiene instruction in orthodontic patients wearing braces for correcting the position of teeth

Submission date
27/01/2022

Recruitment status
No longer recruiting

Registration date
04/02/2022

Overall study status
Completed

Last Edited
20/12/2022

Condition category
Oral Health

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

Plain English summary of protocol
Background and study aims
Orthodontic patients undergo braces treatment for at least 20 months. It is important to maintain good oral hygiene during this period. Therefore, effective oral hygiene instruction must be provided before the treatment starts to prevent future problems such as gingivitis and demineralization of enamel. However, little is known on the duration of knowledge retention of patients after receiving oral hygiene instruction as well as whether an instruction that was given through audiovisual can improve patients' compliance.
This study aimed to assess the effectiveness of an audiovisual method in delivering instruction to orthodontic patients.

Who can participate?
Patients undergoing orthodontic treatment

What does the study involve?
After the placement of the braces, the patient was given instruction either in audiovisual method or written and verbal method. The instruction was given again as a reinforcement after one month, three months and six months during follow-ups. Then patient's oral hygiene status and knowledge retention were assessed.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Orthodontic Clinic, Faculty of Dentistry, Universiti Kebangsaan Malaysia

When is the study starting and how long is it expected to run for?
June 2017 to May 2019

Who is funding the study?
Orthodontic Clinic, Faculty of Dentistry, Universiti Kebangsaan Malaysia

Who is the main contact?
Umi Mardhiyyah Mat Ali, drumi@usm.my

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
UKM PPI/111/8/JEP-2017-575

Study information

Scientific Title
Effects of audiovisual oral hygiene instruction on orthodontic patients: a randomized controlled trial

Study objectives
That there is a significant difference in oral health status between audiovisual and written & verbal instruction methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/09/2017, Research Ethics Committee, The National University of Malaysia (1st Floor, Clinical Block, Hospital Canselor Tunku Muhriz, UKM Medical Centre, Jalan Yaacob Latif, Bandar Tun Razak, 56000, Cheras, Kuala Lumpur Malaysia, +603-91455046/5048; sepukm@ukm.edu.my), ref: UKM PPI/111/8/JEP-2017-575

Primary study design
Interventional

Study design
Single-centre a two-arm parallel randomized clinical trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Oral hygiene of orthodontic patients

Interventions
This clinical trial included 60 orthodontic patients ages ranged from 13 to 40 years old. They were randomized into two groups which are audiovisual method (AV) (n=30) and written and verbal method (WV) (n=30). After placement of the fixed appliances, oral hygiene instruction was given, and at one, three, and six-month followed up as reinforcement. Patients' oral health status was measured using plaque and gingiva indices before placement of fixed appliance as a baseline and at one, three and six months followed up.

Randomization and Blinding: 60 patients receiving fixed appliance treatment were divided into two groups by simple randomization. The audiovisual group (AV) and the written and verbal group (WV) were randomly assigned to 60 pieces of paper, with a sample size of 30 in each group. During patient selection, a researcher's assistant randomly selected papers from an opaque box. The data was gathered and analysed by an examiner who was blinded to the patients' method of instruction during the trial.

Intervention Type
Behavioural

Primary outcome(s)
Oral health status measured using plaque and gingiva indices before placement of fixed appliance as a baseline and at one, three, and six months follow up

Key secondary outcome(s)
Oral hygiene status measured using a questionnaire at one, three and six months

Completion date
21/05/2019

Eligibility

Key inclusion criteria
1. Patient ongoing fixed orthodontic treatment.
2. No previous orthodontic treatment
3. Age range 13 - 30 years old
4. Can fluently speak and read in Malay language

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Patient with any syndromic diseases & cleft lip and palate
2. Patient using any kind of dental prosthesis

Date of first enrolment
10/11/2017

Date of final enrolment
20/06/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Kebangsaan Malaysia
Orthodontic Clinic, Faculty of Dentistry
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300

Sponsor information

Organisation
University Kebangsaan Malaysia Medical Centre

ROR
https://ror.org/01590nj79

Funder(s)

Funder type
University/education

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Umi Mardhiyyah Mat Ali, drumi@usm.my, type of data: oralhygiene status report, data are available now, request by email, suitable for statistical analysis. Consent was obtained from patient, data will be anonymised

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2020	04/02/2022	Yes	No
Participant information sheet			04/02/2022	No	Yes