

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/02/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 20/12/2022	Condition category Oral Health	<input type="checkbox"/> 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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Study design

Single-centre a two-arm parallel randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

See additional files

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 measure

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

Secondary outcome measures

Oral hygiene status measured using a questionnaire at one, three and six months

Overall study start date

20/06/2017

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

Age group

Mixed

Sex

Both

Target number of participants

60

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

Sponsor details

Faculty Of Dentistry
Jalan Raja Muda Abdul Aziz
Kuala Lumpur
Malaysia
50300
+60 392897741
dfdental@ukm.edu.my

Sponsor type

University/education

Website

<http://www.ukm.my>

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

Publication and dissemination plan

Planned publication in high impact peer-reviewed journal

Intention to publish date

27/04/2022

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?
Participant information sheet			04/02/2022	No	Yes
Results article		01/09/2020	04/02/2022	Yes	No