ISRCTN10476938 https://doi.org/10.1186/ISRCTN10476938

Study on the effectiveness of assisted toothbrushing by parents using plaque disclosing toothpaste on preschool children

Submission date
10/07/2025

Recruitment status
No longer recruiting

Registration date
11/11/2025

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Brushing young children's teeth can be tricky—especially when they don't want to cooperate and it's hard to see where the plaque (a sticky, invisible film of bacteria) is on their teeth. Even when parents help their children brush twice a day, as dentists recommend, plaque can still be missed. This study is looking at whether using a special plaque-disclosing toothpaste—which colors the plaque to make it easier to see—can help parents brush their children's teeth more effectively. The study will compare this toothpaste with regular fluoride toothpaste to see which works better for improving children's oral health, behavior during brushing, and parents' confidence and attitudes.

Who can participate?
Children aged 4 to 6 years old who visit the Paediatric Dental Specialist Clinic at UiTM Sungai Buloh can take part if they:
- Can cooperate during a dental check-up
- Are able to spit
- Have no known allergies to toothpaste
- Have parents who help them brush daily and can understand Malay or English
- Have a certain number of baby teeth in each part of the mouth
- Are the only child from their family taking part

Children cannot take part if they:
- Can't spit
- Don't get help from parents with brushing
- Have serious gum problems or certain medical conditions
- Have learning disabilities
- Have parents who don't want to join the study

What does the study involve?
After parents give consent, they'll fill out a questionnaire about their child's behavior and their own views on toothbrushing. A dental check-up will follow, where plaque and gum health will be

assessed using a plaque-coloring paste. Then, the child's teeth will be cleaned. Parents will randomly receive either the plaque-disclosing toothpaste or regular fluoride toothpaste and will be shown how to brush their child's teeth properly. They'll be asked to brush their child's teeth twice a day at home using the given toothpaste. Follow-up visits will happen at 1, 2, 3, and 6 months, with repeat dental checks. At the final visit, parents will fill out the same questionnaire again.

What are the possible benefits and risks of participating?
Benefits:
Parents will get regular updates on their child's dental health. If any problems are found, the child will receive appropriate dental care. The study could also help improve how children's teeth are cared for in the future.
Risks:
There are very few risks. Both types of toothpaste are safe, and the procedures used in the study are routine and gentle.

Where is the study run from?
Faculty of Dentistry, Universiti Teknologi MARA, Sungai Buloh Campus (Malaysia)

When is the study starting and how long is it expected to run for?
December 2023 to June 2026

Who is funding the study?
Universiti Teknologi MARA (Malaysia)

Who is the main contact?
Dr Nurhani Izazie Binti Mohd Fauzi, hanyizazie@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
The effectiveness of parental assisted toothbrushing using plaque disclosing toothpaste in preschool children: a randomized control trial

Acronym
PATPADT

Study objectives
Alternative hypothesis:
1. There is a significant difference of plaque and gingival score in parental assisted toothbrushing on children aged 4 to 6 years old in using plaque disclosing toothpaste compared to commercially available fluoridated toothpaste.
2. There is significant difference of changes on the children's toothbrushing behavior in using plaque disclosing toothpaste compared to commercially available fluoridated toothpaste.
3. There is a significant difference of changes in parental attitude towards child toothbrushing in using plaque-disclosing toothpaste compared to commercially available fluoridated toothpaste.

Null hypothesis:
1. There is no significant difference of changes on the children's toothbrushing behavior in using plaque disclosing toothpaste compared to commercially available fluoridated toothpaste.
2. There is no significant difference of changes on the children's toothbrushing behavior in using plaque disclosing toothpaste compared to commercially available fluoridated toothpaste.
3. There is no significant difference of changes in parental attitude towards child toothbrushing in using plaque-disclosing toothpaste compared to commercially available fluoridated toothpaste.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/12/2024, UiTM Research Ethics Committee (Department of Research and Innovation Level 3 Bangunan Wawasan, Shah Alam, 40450, Malaysia; +603 55442004/2255; recsecretariat@uitm.edu.my), ref: REC/12/2024 (PG/FB/35)

Primary study design
Interventional

Study design
Single-center single-blind parallel randomized controlled trial

Study type(s)
Other, Prevention

Health condition(s) or problem(s) studied
Oral health preventive strategies on children

Interventions
Children age 4 to 6 years old attending Paediatric Dental Specialist Clinic, UiTM Sungai Buloh that full fill our criteria will be invited to participate in our study.

After consent form was signed, the accompanying parents will be required to fill up a validated self-administered M-PACTA questionnaire. Following that, the ICDAS record and gingival score will be taken, followed by the application of GC Tri Plaque ID Gel for plaque score evaluation. All patients will then receive scaling and prophylaxis treatment to standardize their initial condition before the intervention.

The patients will then randomly distribute to one of the following two groups using the SNOSE method.
• Group A: Plaque disclosing toothpaste (Elgydium Plaque Disclosing Toothpaste).
• Group B: Commercially available fluoridated toothpaste (Colgate® Minions Kids Anticavity Toothpaste).

The parents will be advised to assist their children during toothbrushing using the allocated toothpaste in the morning and night daily. Standardized oral hygiene instructions in assisting toothbrushing using the allocated toothpaste will be provided, demonstrated on a model, and in the patient's at every visits. Standardized toothbrushes will also be provided.

Follow-up visits will be arranged at 1-month, 2-month, 3-month, and 6-month from the baseline visit. Oral hygiene reinforcement, plaque and gingival score record will be taken at every follow-up visits.
At the last follow-up visit (6-month), parents will be required to answer the M-PACTA questionnaire again, and to continue with their daily oral hygiene care at home.

Intervention Type
Behavioural

Primary outcome(s)
1. Gingival score is measured using Modified Gingival Index at baseline, and follow-up visits ats 1-month, 2-month, 3-month, and 6-month.
2. Plaque score will be measured using O'Leary Plaque Index (PI). GC-Tri Plaque ID Gel will be applied to disclose the plaque.
3. Children's behaviour and parental attitude in toothbrushing will be evaluated using M-PACTA questionnaire that will be given at baseline at 6-month follow-up visits.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Patient aged 4 to 6 years old and cooperative for dental examination.
2. Patient able to spit.
3. No known allergies to toothpaste ingredients.
4. Patients whose parents assisted in daily tooth brushing.
5. Parents who can understand Malay or English.
6. The patient had at least one primary molar tooth in each quadrant, and at least two anterior primary teeth in the upper and lower jaw.
7. Only one child in a family will be included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
4 Years

Upper age limit
6 Years

Sex
All

Key exclusion criteria
1. Patients unable to spit.
2. Daily tooth brushing was not assisted by the parents.
3. Patients diagnosed with periodontal disease.
4. Patients with medical problems or on medications that can induce gingival manifestations.
5. Patient with learning disability.
6. Child whose parents refuse to participate in the research.

Date of first enrolment
01/03/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Teknologi MARA
Faculty of Dentistry, Sungai Buloh Campus, Selangor Branch
Sungai Buloh
Malaysia
47000

Sponsor information

Organisation
Universiti Teknologi MARA

ROR
https://ror.org/05n8tts92

Funder(s)

Funder type
University/education

Funder Name
Universiti Teknologi MARA

Alternative Name(s)
Universiti Teknologi MARA - UiTM, MARA Technological University, Universiti Teknologi MARA (UITM), Universiti Teknologi MARA in Malaysia, Universiti Teknologi MARA MIMI, Universiti Teknologi MARA | Shah Alam, Malaysia | UiTM, Universiti Teknologi MARA, Malaysia, Universiti Teknologi Mara (UiTM), Malaysia, UiTM – Universiti Teknologi MARA, Universiti Teknologi MARA (UiTM) (Klang, Malaysia), UiTM - Universiti Teknologi MARA, Universiti Teknologi MARA Malaysia, , University of Technology MARA, UiTM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Nurhani Izazie, hanyizazie@gmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants will be required and obtained.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	14/07/2025	No	Yes