

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

|  |  |   |
|--|--|---|
| <b>Submission date</b><br>10/07/2025   | <b>Recruitment status</b><br>Recruiting  | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol                                  |
| <b>Registration date</b><br>11/11/2025 | <b>Overall study status</b><br>Ongoing   | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>14/07/2025       | <b>Condition category</b><br>Oral Health | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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](mailto:hanyizazie@gmail.com)

## Contact information

**Type(s)**

Public, Scientific, Principal investigator

**Contact name**

Dr Nurhani Izazie Mohd Fauzi

**ORCID ID**

<https://orcid.org/0009-0003-9146-2672>

**Contact details**

NO 50, Jln TPS2/18B, Taman Pelangi Semenyih 2

Semenyih

Malaysia

43500

+60 17-6620932

[2024483962@student.uitm.edu.my](mailto:2024483962@student.uitm.edu.my)

## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

Nil known

## 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)

### Study design

Single-center single-blind parallel randomized controlled trial

### Primary study design

Interventional

## 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 at 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](mailto: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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Participant information sheet</a> |                               |              | 14/07/2025 | No             | Yes             |
| <a href="#">Participant information sheet</a> | Participant information sheet | 11/11/2025   | 11/11/2025 | No             | Yes             |