Efficacy of regular, musical and electric toothbrushes in plaque removal in children – A randomized clinical trial

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STUDY PROTOCOL

Study design

This study is designed as a randomized clinical trial to compare the efficacy of three types of toothbrushes - regular, musical, and electric - in removing supragingival plaque among children aged 6-12 years. The study duration was set for 2 months, beginning on January 15, 2024.

Ethical approval

Ethical approval (no. 07-06-43) was sought from the Local Committee of Bioethics at Jouf University, KSA. All necessary approvals were obtained prior to the initiation of the study to ensure ethical compliance and participant safety.

Sample size calculation

Sample size estimation was done by using GPower software (version 3.0). Sample size was estimated for F test and ANOVA: Repeated measures, between factors, for 3 groups and4follow up measurements was chosen. A minimum total sample size of 102 was found to be sufficient for an alpha of 0.05, power of 95%, 0.25 as effect size. As the proposed study is a trial of 60 days duration with 4 repeated measurements, so keeping in mind a 10% attrition, the sample size was inflated to 111 (37 per group).

Participant selection

A total of 111 healthy children participated in the study, each selected based on specific inclusion and exclusion criteria. Written consent was obtained from the parents or guardians of all participants.

Inclusion criteria

- Children aged 6-12 years;

- Cooperative children; and
- Children with a minimum of twenty teeth.

Exclusion criteria

- Children with poor oral hygiene characterized by extrinsic stains or calculus deposits;
- Presence of any oral lesions;
- Presence of malocclusion; and
- Medically compromised patients.

Randomization and allocation

Participants were randomly allocated to one of three groups (n = 37 participants per group) using a computer-generated randomization sequence managed by the first examiner. The groups are defined as follows:

- **Group 1 (Regular Toothbrush):** Oral-B Chhota Bheem Toothbrush.
- **Group 2 (Musical Toothbrush):** Aqua White Musical Chhota Bheem Toothbrush.
- **Group 3 (Electric Toothbrush):** Oral-B Star Wars Kids Electric Toothbrush.

Table 1 allocate steps for randomization of the process.

Blinding

To reduce bias, the second examiner, responsible for recording clinical parameters, was blinded to the group assignments.

Intervention

Participants and their guardians were instructed in the horizontal scrub technique and asked to adhere to a brushing regimen of two minutes, twice daily, for 45 days. Standard fluoride toothpaste and a diary for recording brushing experiences was also provided. Guardians supervised brushing to ensure compliance and prevent the use of other oral hygiene measures.

Outcome measures

The primary outcome measure is the Plaque Index (Quigley and Hein). Plaque assessments was conducted at baseline (day 0) and on days 15, 30, and 45. Participants were refrain from oral hygiene for 24 hours before each recall visit. During each visit, they were supposed to brush under supervision for two minutes with their assigned toothbrush and toothpaste. Plaque disclosure was achieved using a 5 mL disclosing solution for 15 seconds, followed by rinsing with 10 mL water for 10 seconds.

Data collection

All clinical data was recorded using a standardized proforma. The principal investigator ensured the accuracy and confidentiality of the data, entering it into a data sheet immediately after collection. Confidentiality was maintained by anonymizing survey responses and securely storing the data.

Data management plan

The data management plan includes continuous monitoring by the principal investigator, secure transfer and storage of data, and adherence to safety and ethical protocols.

Potential risks and benefits

The study presents minimal risks, mainly limited to potential discomfort from brushing or allergic reactions to toothpaste. However, the potential benefits include improved oral hygiene awareness and a reduction in plaque, contributing to better oral health outcomes for the participants.

This detailed methodology ensures a clear, structured approach to conducting the trial, adhering to CONSORT[13] guidelines for reporting randomized clinical trials. The study, self-funded, aimed to contribute valuable insights into paediatric dental care practices and enhance oral health education for parents and guardians, aligning with the goals of the CONSORT guidelines for transparent reporting of clinical trials.