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Effectiveness of daily use of plaque-disclosing mouth rinse on children's oral health

Submission date
21/08/2024

Recruitment status
No longer recruiting

Registration date
22/08/2024

Overall study status
Completed

Last Edited
22/08/2024

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Dental caries (tooth decay) is the most common oral disease, with prevalence rates in the Middle East and North Africa reaching 17-88.8%. Dental plaque leads to caries, gingivitis (mild gum disease), and periodontitis (serious gum infection). Preventing dental caries includes improving diet, explaining oral hygiene instructions to individuals, and applying fluoride. Various mechanical and chemical methods control dental plaque, with toothbrushing being the most common mechanical self-care method. However, since dental plaque is not visible, methods capable of disclosing plaque are used to help improve plaque control. Plaque-disclosing agents are selective dyes to detect dental plaque and are commercially available in several pharmaceutical forms, such as tablets, mouthwashes, and toothpaste. Plaque-disclosing agents include iodine, basic fuchsin, food dyes, erythrosine, and fluorescein dyes, and they must stay for an adequate period, be biocompatible, non-allergic, non-irritating, flavored, and not be washed out instantly. However, commercially available plaque-disclosing agents require application by a physician, are not suitable for use in children, or have plaque coloration similar to the oral mucosa (mouth tissues). In addition, there have been several concerns regarding the safety of repeated use of erythrosine.
FD&C Blue #1 and FD&C Blue #2 are among the safest colorants according to the FDA, are low cost, are resistant to damage by light, oxidizing agents, or changes in pH, and thus have good color stability. This study aims to compare health education alone, using plaque-disclosing agents periodically by a dentist, and the home use of the plaque-disclosing mouth rinse made with FD&C Blue #1 and FD&C Blue #2 in self-assessment by children aged 8-10 years. The aims are to improve plaque control and thus help improve oral health in children.

Who can participate?
Healthy children aged 8-10 years with plaque index ≤2 according to the Turesky modified Quigley-Hein plaque index (TMQHPI)

What does the study involve?
Participants were randomly allocated into three groups:
Group 1 (the control group) were given oral hygiene instructions only.
Group 2 (self-assessment at the clinic) were given oral hygiene instructions and a dentist used a plaque-disclosing agent to self-assess the participants' oral hygiene during follow-up sessions.

Group 3 (home self-assessment with mouth rinse) were given oral hygiene instructions and a home plaque-disclosing mouth rinse formulated for this study was used for self-assessment.

What are the possible benefits and risks of participating?
Participants will benefit from disclosing dental plaque and improving their oral health. However, there is a risk of disclosing agents dyeing the mouth tissues.

Where is the study run from?
Damascus University (Syria)

When is the study starting and how long is it expected to run for?
September 2021 to June 2024

Who is funding the study?
Damascus University (Syria)

Who is the main contact?
Dr Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Efficacy of daily use of plaque-disclosing mouth rinse on children's oral health: a randomized controlled trial

Study objectives
The null hypothesis is that the three methods used in the study were equally effective in controlling dental plaque.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2021, The Biomedical Research Ethics Committee (Mezzeh highway, Damascus, N/A, Syria; +963 (11) 33923223; dean.dent@damascusuniversity.edu.sy), ref: 3392

Study design
Single-blinded randomized parallel-group active control trial with three arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic

Study type(s)
Other, Prevention

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Dental plaque

Interventions
Participants were randomly allocated into three groups using a simple randomization method and online randomization software (https://www.randomizer.org/) in a ratio of 1:1:1:1:
Group 1 (control group): Given oral hygiene instructions only.
Group 2 (self-assessment at the clinic): Given oral hygiene instructions and utilizing a plaque-disclosing agent by a dentist to self-assess the participants' oral hygiene during follow-up sessions.
Group 3 (home self-assessment with mouth rinse): Given oral hygiene instructions and utilizing home plaque-disclosing mouth rinse formulated for this study for self-assessment.

Plaque disclosing mouth rinse was formulated at the Faculty of Pharmacy, Damascus University. Equal amounts of FD&C Blue #1 and FD&C Blue #2 powder at a concentration of 0.5 mg/100 mL and the excipient was prepared using hydroxypropylmethylcellulose, citric acid, sodium benzoate, sorbitol, and distilled water. A pilot study on four samples was conducted to confirm that the formulated plaque-disclosing mouth rinse only stains the dental plaque without staining the gingival tissues and oral mucosa, is comfortable, has acceptable taste, does not get washed out immediately but the coloured area is removed by adequate brushing.

Participants from a primary school in Damascus City were randomly assigned into three groups. Dental plaque accumulation was measured at the baseline (t0), after 2 weeks (t1), and after 4 weeks (t2) for each participant in each group utilizing the disclosing solution (Mira2Ton®, Hager & WerkenGmbH & Co. KG). The TMQHPI scores were as follows:
0 = No plaque
1 = Scattered areas of plaque at the gingival margin
2 = A continuous thin band of plaque at the gingival margin (≤1 mm)
3 = A band of plaque wider than 1 mm but covering less than a third of the crown
4 = A band of plaque covering more than one-third and less than two-thirds of the crown
5 = Plaque covers two-thirds of the crown or more
For group 1, oral hygiene instructions were given utilizing visual aids. Oral hygiene instructions explained the concept of oral health, dental caries, its causes and consequences, and prevention methods, along with brushing instructions and information related to diet. A toothbrush was given to each child, emphasizing the necessity of committing to brushing twice a day for two minutes by teaching them the Modified Bass technique. For Group 2, oral hygiene instructions were given as for Group 1, in addition to applying the plaque-disclosing agent to self-evaluate the child's oral hygiene during follow-up sessions after explaining the implications of plaque index scores. For Group 3, oral hygiene instructions were given as for Group 1, in addition to distributing formulated plaque-disclosing mouth rinse to self-evaluate the child's oral hygiene, used before brushing once a day for a minute and evaluating dental plaque accumulation.

Intervention Type
Other

Primary outcome measure
Dental plaque accumulation measured using the Turesky modified Quigley-Hein plaque index (TMQHPI) at baseline (t0), after 2 weeks (t1), and after 4 weeks (t2)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
20/09/2021

Completion date
05/06/2024

Eligibility

Key inclusion criteria
1. Healthy children aged 8-10 years
2. Plaque index ≤2, according to the Turesky modified Quigley-Hein plaque index (TMQHPI)

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
8 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
90

Total final enrolment
90

Key exclusion criteria
1. Anterior resin composite restorations
2. Extensively decayed first permanent molars
3. Undergoing orthodontic treatment
4. Allergies to food colorants

Date of first enrolment
02/10/2023

Date of final enrolment
02/06/2024

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh Highway
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

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ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/11/2024

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

IPD sharing plan summary
Available on request