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The effect of an oral hygiene regimen on periodontal health

Submission date 27/04/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/05/2018	**Overall study status** Completed	
Last Edited 16/06/2025	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Periodontal (gum) disease is common worldwide and is expected to increase due to increased life expectancy. Risk factors identified are mainly poor oral hygiene, poor diet, tobacco use, diabetes and other conditions. It can lead to tooth loss which has many implications such as negative impacts on nutrition and quality of life. The main approach to help prevent periodontal disease is effective daily oral hygiene. Numerous products have been designed to enhance plaque removal and inhibit plaque, including electric toothbrushes, chemotherapeutic pastes and rinses and interdental cleaning aids. The aim of this study is to assess the long-term safety and efficacy of a combination oral hygiene regimen on gingivitis (gum inflammation) among individuals with periodontitis over a period of 2 years.

Who can participate?
Generally healthy volunteers aged 18 and over with periodontitis

What does the study involve?
Participants are randomly allocated to either the regimen group (including antimicrobial paste, rinse, floss and an electric toothbrush) or a control group (standard anti-cavity toothpaste and a regular manual toothbrush). Participants are requested to use their assigned products twice daily at home for the duration of the study (2 years). At the start of the study and months 6, 12, 18 and 24 participants receive oral exams, and gingival inflammation, bleeding and periodontal measurements are assessed. Both groups receive supragingival dental prophylaxis (cleaning above the gum line) every 6 months.

What are the possible benefits and risks of participating?
The study is designed to assess if the participants in the regimen group experience an improvement in oral health. However, there is no general direct immediate benefit to the participants from taking part in this study. Nevertheless, their participation may help in the development of products that aim to improve periodontal health. There are no notable risks involved with participating.

Where is the study run from?
Hadassah - Hebrew University Medical Center (Israel)

When is the study starting and how long is it expected to run for?
February 2014 to February 2016

Who is funding the study?
Procter and Gamble Company (USA)

Who is the main contact?
Prof. Dr Avraham Zini

Contact information

Type(s)
Scientific

Contact name
Prof Avraham Zini

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Additional identifiers

Protocol serial number
Clinical Protocol 2013078

Study information

Scientific Title
Long-term use of combination oral hygiene on gingival and periodontal health: a pilot study

Study objectives
The aim of this study is to assess the long-term safety and efficacy of a combination oral hygiene regimen on gingivitis among individuals with concomitant periodontitis over a period of 2 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hadassah Medical Organization Helsinki Committee, 24/12/2013, IRB Approval #: 0482-13-HMO

Primary study design
Interventional

Study design

Single-center randomized controlled examiner-blind two-treatment parallel study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Oral concomitant periodontitis

Interventions
Participants are stratified based on Screening mean Probing Pocket Depth, mean Gingival Bleeding Index, mean age, gender and tobacco use. Within strata, participants are randomly assigned equally to either the regimen group (antimicrobial paste, rinse, floss and an electrical toothbrush) or the control group (standard anti-cavity toothpaste and a regular manual toothbrush).

Participants of the regimen group are instructed to brush their teeth with the assigned electrical toothbrush and dentifrice for two minutes twice a day (morning and evening) following the manufacturer's usage instructions and to floss the whole mouth once daily for the duration of the study. Participants rinse with water after brushing to remove remaining toothpaste and then rinse with 20ml of the mouth rinse for 30 seconds. Subjects used only the treatment products in place of normal oral hygiene products for the duration of the study.

Participants of the control group are instructed to brush their teeth with the assigned products twice daily (morning and evening) in their customary manner. Subjects are instructed to rinse with water after brushing. Participants use only the treatment products in place of normal oral hygiene products for the duration of the study (they are allowed to continue using floss but they are instructed not to add/change any other oral hygiene products).

Participants are requested to use their assigned products at home for the duration of the study (2 years).

Intervention Type
Other

Primary outcome(s)
Measured at baseline, month 6, 12, 18 and 24:
1. Gingival inflammation, measured by Modified Gingival Index
2. Bleeding, measured by Gingival Bleeding Index
3. Periodontal measurements (Gingival Recession and Probing Pocket Depth)

Key secondary outcome(s)
No secondary outcome measures

Completion date
11/02/2016

Eligibility

Key inclusion criteria
1. Give written informed consent and receive a copy of their consent
2. Be between the ages of 18 and 65

3. Be in good general health as determined by the Investigator/designee based on a review of the medical history/update for participation in the study
4. Possess a minimum of 16 natural teeth (excluding third molars) with facial and lingual scorable surfaces
5. Have at least 20 bleeding sites (sum of sites with a score of 1 or 2 on the GBI index)
6. Have at least: 3 eligible healthy sites (PPD <3 mm, no bleeding), 3 eligible gingivitis sites (PPD < 3 mm, bleeding), and 3 eligible periodontal sites (PPD 3-6 mm, bleeding)
7. Agree to delay any elective dentistry until study completion, including additional dental prophylaxes outside the study protocol
8. Agree to refrain from using any non-study oral hygiene products for the study duration (subject will be allowed to continue using floss but they will be instructed not to add/change any other oral hygiene products, including whitening products etc)
9. Agree not to participate in any other oral care clinical study for the duration of this study
10. Agree to return for their scheduled visits and follow study procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Severe periodontal disease, as characterized by purulent exudate, generalized mobility, and /or severe recession
2. Active treatment for periodontitis
3. Having a medical condition requiring antibiotic pre-medication prior to dental procedures
4. Fixed facial or lingual orthodontic appliances or removable partial dentures
5. Antibiotic or chlorhexidine use or anti-inflammatory medications within two weeks prior to Screening visit
6. Self-report nursing, pregnancy, or intent to become pregnant during the study
7. Dental prophylaxis within two months prior to the Screening visit
8. Any diseases or conditions that could be expected to interfere with the subject safely completing the study

Date of first enrolment
16/02/2014

Date of final enrolment
27/02/2014

Locations

Countries of recruitment
Israel

Study participating centre
Kibbutz Na'an, Israel
Israel
76829

Sponsor information

Organisation
Procter & Gamble

ROR
https://ror.org/04dkns738

Funder(s)

Funder type
Industry

Funder Name
Procter and Gamble

Alternative Name(s)
Procter & Gamble, PandG, The Procter & Gamble Company, P and G, Procter & Gamble Company, P&G

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because if the raw data is available but not analyzed appropriately by qualified experts in the area, it may lead to misinterpretation of the results. Study protocol, statistical analysis plan, and other additional documents are not intended to become available online.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	16/06/2025	Yes	No