

Evaluation of the Prebiotic Effect of New Dentifrice Formulations In Healthy Adults

ACTRN12623000893606

Status	RECRUITING
Sponsor	The University of Melbourne
Enrollment	40 participants

Plain Language Summary

Gum disease (gingivitis) is caused by a buildup of plaque on teeth and the bacteria that live in it. This study is testing whether a special toothpaste called GC MI Paste One Perio — which contains a milk-derived protein complex (CPP-ACP) plus stannous fluoride — has a different effect on gum health and the bacteria in your mouth compared to a standard stannous fluoride toothpaste (Colgate Total SF).

Participants will be randomly assigned to brush with one of the two toothpastes three times a day for 21 days, with no other oral hygiene products allowed during this time. Gum health, plaque levels, and the types of bacteria present in the mouth will all be measured before and after. The idea is that the CPP-ACP ingredient might act like a prebiotic, encouraging a healthier mix of mouth bacteria.

You may be eligible if you are aged 18 to 75, have at least 20 natural teeth, have some gum inflammation and plaque build-up, and are in good general health. People with orthodontic braces, crowns on most front teeth, gum disease requiring clinical treatment, or allergies to milk protein or tin are not eligible. The study is based at the University of Melbourne.

Key Eligibility Criteria

Inclusion (9)

- To be eligible to participate in this study, an individual must meet all of the following criteria:
- Ability to understand, and willingness and ability to read and sign, the informed consent form.
- Age range: 18 to 75 years old.
- Good general health.
- Minimum of 20 natural teeth.

... and 4 more (see full listing online)

Exclusion (10)

- Allergy to milk protein, tin or other ingredients in toothpaste products.
- Orthodontic appliances or removable prostheses.
- Veneers, or more than one incisor with a prosthetic crown.
- Gross oral pathology (including periodontal disease {Community Periodontal Index of Treatment Needs [CPITN] greater than or equal to 3} and tumours of the soft or hard oral tissues).
- Chronic disease with concomitant oral manifestations (e.g., diabetes [irrespective of level of control], human immunodeficiency virus infection or acquired immunodeficiency syndrome, use of medications associated with gingival hyperplasia).

... and 5 more (see full listing online)

Locations (1 total)

VIC, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12623000893606>

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