Key Drivers for Oral Freshness

Published: 27-05-2013
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The main objective of this study is to test which combinations of tooth paste ingredients enhance the feeling of freshness after tooth brushing.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38787

Source
ToetsingOnline

Brief title
Freshness

Condition

- Other condition

Synonym
oral freshness

Health condition

in-mouth freshness after teeth brushing

Research involving
Human

Sponsors and support

Primary sponsor: NIZO food research B.V.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: gutometer, oral freshness, toothpaste

Outcome measures

Primary outcome

oral freshness

Secondary outcome

not applicable

Study description

Background summary

Regular tooth brushing is of utmost importance for oral health to remove dental plaque and food from the teeth, assists in suppressing halitosis, and delivers active ingredients (mainly fluoride) to help prevent tooth and gum disease. The feeling of oral freshness after tooth brushing is an important driver for humans to regularly brush their teeth. In this study we test which combinations of tooth paste ingredients enhance the feeling of freshness after tooth brushing. In a Randomized Complete Block Design Central Location Test, the subjects will brush their teeth using a modified toothbrush that allows the delivery of tooth paste ingredients in-mouth by means of a pumping device (*gustometer*). Subjects will test a total of 7 different tooth paste ingredient combinations in a total of 7 sessions with one session per week. *Freshness* is recorded before tooth brushing and 7 times after tooth brushing at 10-minutes intervals on a VAS denoted *not fresh at all* and *the freshest sensation possible* on the extremes. Testing will take place in the morning; participants are asked to come in without having consumed any food/drink or participated in any form of oral hygiene since 12:00 am. Participants will dispense maximum 1.5 g toothpaste product onto the toothbrush, and brush teeth as they normally would for maximum 45 seconds. While brushing is occurring, the ingredients to be used as stimuli will be dispensed into the mouth via the Teflon tubing connected to the toothbrush head. The quantity of ingredients used as stimuli in the mouth will not exceed the maximum concentrations commonly found in toothpaste products at any point during the brushing time, when considering the toothpaste base and any other stimuli being used. Ingredients used as stimuli will be dispensed into the mouth individually, in combination or alternation with others. The toothpaste base and stimuli ingredients will be spit out at the end of the maximum 45 seconds product usage

period. Participants will be asked to complete a questionnaire and/or interview following the product usage. Each session lasts 1.5h and starts at 8.00am or 8.30am. Subjects receive a free breakfast (bread, butter, jam, cheese, ham, boiled eggs, milk, coffee, tea, water, all ad libitum) immediately at the end of each test. They are asked to fill in a food diary the day before each test to record their food and beverage consumption.

Study objective

The main objective of this study is to test which combinations of tooth paste ingredients enhance the feeling of freshness after tooth brushing.

Study design

In a Randomized Complete Block Design Central Location Test, the subjects will brush their teeth using a modified toothbrush that allows the delivery of tooth paste ingredients in-mouth by means of a pumping device (*gustometer*). Subjects will test a total of 7 different tooth paste ingredient combinations in a total of 7 sessions with one session per week. *Freshness* is recorded before tooth brushing and 7 times after tooth brushing at 10-minutes intervals on a VAS denoted *not fresh at all* and *the freshest sensation possible* on the extremes. Testing will take place in the morning at 8:00am or 8:30am; participants are asked to come in without having consumed any food/drink or participated in any form of oral hygiene since 12:00 am. Participants will dispense maximum 1.5 g toothpaste product onto the toothbrush, and brush teeth as they normally would for maximum 45 seconds. While brushing is occurring, the ingredients to be used as stimuli will be dispensed into the mouth via the Teflon tubing connected to the toothbrush head. At the end of each test, subjects undergo an exit interview and receive a breakfast. Subjects have to fill in a food diary the day before each test.

Intervention

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Study burden and risks

The participants have to visit the test location 7 times, once a week during 7 weeks. They arrive in a fasting, non-fresh (non-brushed teeth) state. All ingredients used are already commonly used in tooth paste products. Except for increased feelings of freshness no side effects are expected. Besides, no invasive measurements will be performed. Therefore, the burden for the subjects is minimal and the risks associated with participation are very low. Fasting prior to the experiment is required in order to prevent that food intake affects the freshness scores. Similarly, people are asked not to use any dental care products prior to the experiment. In order to minimise the discomfort subject, all session are held in the early hours of the morning and participants will receive a meal before leaving NIZO food research. The subjects are paid 175,- upon completion of the study. The incentives are proportionally to the number of sessions, which the subject attends.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• age 18-34
• visit the dentist 1 or more times a year for check-up
• use one or more of the following products two or more times a day: toothpaste, mouthwash, gums, mints, breath spray, breath strips.
• Sign informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• smoker
• taking any medication that may interfere with their sensation of taste, aroma and mouthfeel
• not having full dentures (less than 20 teeth)
• wear braces
• currently experiencing oral irritation or are using oral anaesthetics
• currently participating in oral surgery or extensive dental work
• having allergies to any oral care products or their ingredients

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2013
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44035.081.13