Queensland Government

Oral Health Services
Metro North Hospital and Health Services

Participant Information Sheet – Parent/Guardian

Metro North Oral Health Services

Project Title: A controlled trial to evaluate the influence of CPP- ACP – Cranberry toothpastes in effecting an ecological change in the oral plaque microbiome

Principal Investigators: Prof. Laurence Walsh; Assoc. Prof. David Healey; Nebu Philip; Dr. Shaneen Leishman.

Part A: What does the child's participation involve?

1. Introduction

This is an invitation for the child/teenager in your care to take part a research project that is testing new preventive toothpastes for tooth decay in orthodontic patients. This Participant Information Sheet/Consent Form gives you details about the research project. Knowing what is involved will help you decide if you want the child/teenager to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not the child/teenager can take part, you might want to talk about it with a relative, friend or the child/teenager's local doctor.

Participation in this research is entirely voluntary. If you do not wish for the child/teenager to take part, they do not have to. He/she will continue to receive the best possible dental care whether or not they take part.

If you decide you want the child/teenager to take part in the research project, you will be asked to sign the Consent Form. By signing it you are telling us that you:

- Understand what you have read
- Consent to the child/teenager taking part in the research project
- Consent for the child/teenager to have the treatments that are described
- Consent to use of the child/teenager's personal information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research?

This research is being conducted by The University of Queensland School of Dentistry. The project aims to find out whether brushing with new preventive toothpastes can change bacterial composition of dental plaque deposits on teeth and make them less likely to induce tooth decay.

Two new toothpastes are being investigated, one containing casein phosphate-amorphous calcium phosphate (CPP-ACP), and the other containing a combination of CPP-ACP and highly-purified organic cranberry extracts. CPP-ACP is a complex of proteins and minerals derived from cow's milk that is scientifically proven to prevent tooth decay, erosion, and sensitivity. Cranberry extracts, long used in foods and juices, have been shown to inhibit the oral bacteria responsible for causing tooth decay in laboratory studies.

CPP-ACP has been successfully used in oral care products in Australia to prevent tooth decay when used as a topical crème (applied on teeth after brushing with a fluoridated toothpaste) or in chewing gums. The two CPP-ACP oral care products to be used in this project are meant to be used as regular toothpastes for routine twice-daily toothbrushing. Both these new toothpastes contain fluoride at concentrations consistent with regular commercially available toothpastes and meet all guidelines required to maintain oral hygiene when used as instructed.

3. What does participation in this research involve?

If your child/teenager is eligible and you consent to their participation, he/she will be randomly allocated to one of three toothpaste groups: a CPP-ACP toothpaste group; a CPP-ACP – Cranberry toothpaste group; and a fluoridated toothpaste group without either CPP-ACP or cranberry that will serve as the active control group. It will not be known which of the toothpaste treatments your child/teenager is receiving. The study clinician will also not know (a double-blind study). However, in certain circumstances the study clinician can find out which treatment the participant is receiving. This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study clinicians/researchers or participants jumping to conclusions. The toothpaste group your child/teenager is in will only be revealed after the completion of all the analysis of the study.

Your child/teenager will be asked to routinely brush their teeth twice daily (morning and night) with their allocated toothpaste. Both the test toothpastes and the placebo toothpaste will contain an amount of fluoride which is consistent with commercially available toothpastes. All toothpastes will be supplied free of charge to participants for the duration of their involvement in the study.

To determine the effects of the toothpastes on dental plaque deposits, plaque swab samples will be collected from the participant's teeth on two separate occasions. The first dental plaque sample will be collected at baseline just before the child/teenager starts using his/her allocated toothpaste. The second dental plaque sample will be collected after 4 weeks of using the toothpaste. On both occasions, plaque samples will be collected by swabbing the upper and lower teeth with a microbrush. Prior to the plaque sample collection, your child/teenager will be instructed not to brush in the

morning and to refrain from food/drink for two hours before the plaque collection. Both plaque sample collections can be done to coincide with your child/teenager's scheduled orthodontic appointment 4 weeks apart.

4. What will happen to the collected plaque samples?

The plaque samples collected will be sent to The University of Queensland research laboratory at the Herston Oral Health Centre. The samples will be tested for the presence of decay-causing bacteria and general oral bacteria and how these levels change over the 4 weeks of the study. At the end of the analysis, any remaining oral plaque samples will be destroyed in compliance with biological safety requirements. You will not be advised of the individual results of your child's plaque sample.

5. Does the child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for the child/teenager to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw the child/teenager from the project at any stage. If you do decide that the child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. Your decision that the child/teenager can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine orthodontic/dental treatment, relationship with those treating them, or their relationship with *Metro North Oral Health Services.*

6. Other relevant information about the research project

In total, a little over 60 orthodontic patients will be recruited to participate in this project. This project is a collaborative project between The University of Queensland School of Dentistry and Metro North Oral Health Services.

7. What are the possible benefits of taking part?

CPP-ACP topical crèmes have been proven to be very effective in preventing white spot lesions (first stage of tooth decay) that often develop during the course of orthodontic treatment. Toothpastes containing CPP-ACP are expected to offer the same benefits and will thus be particularly helpful for patients undergoing orthodontic treatment.

No monetary benefits will be provided. However, resources such as toothbrushes and toothpastes will be issued free of charge during the trial period.

8. What are the possible risks and precautions of taking part?

CPP-ACP toothpaste is a milk-based product which has been shown to be very safe and effective against dental decay. It works by protecting the teeth against bacterial acids. However, children/teenagers who are allergic to cow's milk should not use the CPP-ACP toothpaste. If your child/teenager is identified as having an allergy to cow's milk during the study, immediately stop using the toothpaste supplied and notify us. Cranberry extracts added to one of the test toothpastes is a commonly used natural product and is not

expected to have any safety issues. Like for regular toothpastes, excessive swallowing of the test toothpastes should be avoided. All dental products issued should be kept out of reach of children.

9. What if I withdraw the child/teenager from this research project?

If you decide to withdraw the participant from the project at any stage, please notify a member of the research team. You should be aware that data collected up to the time of withdrawal will form part of the research project. If you do not want this, you must tell them before the participant joins the research project.

10. What happens when the research project ends?

After the research finishes, the trial toothpaste will no longer be available. You will be encouraged to have your child/teenager brush twice daily with commercially available fluoridated toothpaste.

At the end of the research study, all participants who completed the study will be emailed flyers on the overall results of the study.

Part B: How is the research project being conducted?

1. What will happen to information about the child?

By signing the consent form you consent to the relevant research staff collecting and using personal information about the child/teenager for the research project. The personal information collected for this research project is restricted to name, age, gender and contact information of the participant. Any information obtained in connection with this research project that can identify the child/teenager will remain confidential and securely stored. The child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the child/teenager cannot be identified.

In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to the participant's information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact a study team member if you would like to access the participant's information.

2. Complaints and Compensation

If the participant suffers any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical/dental treatment for the participant. If the participant is

eligible for Medicare, they can receive any medical treatment required to treat the injury or complication free of charge, as a public patient in any Australian public hospital.

3. Who is organising and funding the research?

This research project is being conducted and supervised by Prof. Laurence Walsh at The University of Queensland School of Dentistry. The project is being funded by Prof. Walsh internal research grants. The test toothpastes being trialed in this study are being provided by GC Corporation based in Japan. This company has licensed the CPP-ACP technology for dental products and is the sole global manufacturer of CPP-ACP dental products. GC Australia role in this project is restricted to providing the trial toothpastes and they have placed no constraints on publishing the results obtained from the clinical trial.

A positive outcome would be advantageous for GC Corporation (through potential future product sales). You will not benefit financially from the child's involvement in this research project even if, for example, the child's samples (or knowledge acquired from analysis of the samples) prove to be of commercial value. No member of the research team will receive a personal financial benefit from the child's involvement in this research project (other than their ordinary wages).

4. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). This study adheres to the Guidelines of the ethical review process of the HREC of Metro North Health and The University of Queensland and the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. Whilst you are free to discuss your participation in this study with project staff (please see below), if you would like to speak to an officer of the University not involved in the study, you may contact the UQ Ethics Coordinator on 3365 3924.

5. Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project, you can contact the following people:

For further details about this research project or to report any adverse effects on using the trial toothpastes, you may contact:

Research project contact person

Name	*Laurence Walsh*
Position	*Professor of Dental Science*
Telephone	*0401 990 555*
Email	*l.walsh@uq.edu.au*

For matters relating to research at the site at which the child/teenager is participating, the details of the local site person are:

Site complaints contact person

Name	***Jacqueline Robinson***
Position	*Research Governance Officer, Metro North Hospital and Health Service HREC, Royal Brisbane and Women's Hospital*
Telephone	*3646 8579*
Email	RBWH-RGO@health.qld.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC Office contact

Name	*Anne Carle*
Position	*HREC Coordinator and Manager, Metro North Hospital and Health Service HREC, The Prince Charles Hospital*
Telephone	*3139 4500*
Email	ResearchTPCH@health.qld.gov.au