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RESEARCH PARTICIPANT INFORMATION SHEET

A Study to investigate the impact of behavioural change modification using 3D intra-oral gingival imaging combined with a toothpaste indicated for gingivitis, to deliver an optimized standard of care to improve gingival health.

You are being invited to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others, such as family, friends, or your dentist, if you wish. The study dentist will go through this Research Participant Information Sheet with you and answer any questions you may have. Please ask if there is anything that is not clear or if there is anything you would like more information about. Then please take as much time as you need to decide whether you wish to take part or not. At this point we would like to thank you for your interest in this research study and for considering taking part.

PART 1

What is the purpose of the study? Why is this study being carried out?

Many people suffer from gum disease (gingivitis) which can impact on their daily life. Gingivitis is generally assessed by a clinical examination of the gums by your Dentist or Hygienist, who look for visual signs of gum inflammation such as redness, bleeding and swelling or a combination of all these.

With the increased use of technology within the dental profession, scanners are starting to be used routinely to record 3D images of the mouth. They can capture the teeth (hard issue) and gums (soft tissues) accurately and in great detail. These images can be used by Dentists/Hygienists as an aid when undertaking oral health assessments, and as they are available for future reference, they are suitable for monitoring a patient's progress over

several dental appointments/years. As well as benefitting the dental team these images could also help when providing oral hygiene advice for patients. The scans can capture the whole mouth including the very back and could be used to show patients exactly where they need to clean a bit better. The provision of oral hygiene advice so that patients understand exactly what they need to do is key in helping them improve their tooth and gum cleaning techniques and in turn improve the health of their teeth and gums.

The aim of this study is to find out if using 3D scans and associated oral hygiene advice together with toothpaste designed for healthy gums can improve overall gum health more than the use of standard oral hygiene advice given without the aid of the 3D scans and the participants preferred toothpaste.

This study is being sponsored by the University of Bristol and funded by GlaxoSmithKline Consumer Healthcare. The study has been approved by the East of Scotland Research Ethics Service. The researchers themselves are not being paid by the Sponsor or funder of the study for the conduct of the trial.

Why have I been invited to take part?

You have been invited to take part in this study because you have previously expressed an interest in our research, and you asked to be added to the Dental Clinical Trials Database to be contacted for future studies, or because you have contacted us as you have seen a poster/advert for this study. Approximately 80 people will be invited to take part in this study.

Do I have to take part in this study?

No, you are entirely free to choose, and if you do decide to take part but then then change your mind, you are free to stop your participation in the study at any time without giving a reason.

What will happen to me if I take part in this study / what will I have to do?

If you agree to participate in this study, you will be asked to confirm you have read the participant information sheet and then to sign the consent form confirming you are happy to take part – this needs to be done before any study procedures can begin.

To complete this study, you will need to attend 4 study visits over a 6-month time-period. It is anticipated that the first visit will last approximately 90 minutes, and then visits 2, 3 and 4 will last approximately 40 minutes. All clinical assessments will be performed by the University Dental Clinical Trials Unit (CTU) Research Dentists. Appointments may be conducted at The Bristol Dental Hospital, its sister site South Bristol Community hospital or in a Bristol General Dental Practice in Redland.

Study Visits

Visit 1:

Part A - Screening. Once you have agreed to take part, and given your signed consent to participate, the Study Dentist will ask you a few questions including your gender, date of birth, ethnicity and then ask you about your medical history including any medication you may take - this will be recorded in your study notes. The dentist will show you a list of toothpaste ingredients to see if you know you are allergic to any of them, if you are you will not be able to take part in the study. The dentist will then examine your teeth and mouth and ask you a set of standard questions to assess if you fit the criteria to take part in the study. If you have any condition that might influence your gum health you will not be able to take part in the study.

During the oral examination, should any abnormalities in the oral hard (teeth) or soft (gum) tissues be detected, we will advise you to seek further medical advice from your dentist or GP.

> **Please note** - not everyone who attends the screening visit and is assessed for the study will be eligible to take part.

Part B - Baseline assessment. If you successfully fulfil all the requirements to take part in the study, you will then be asked to fill in a questionnaire about the tooth cleaning routine and products you normally use at home and a gum health experience questionnaire.

All participants will then undergo a standardised dental examination and have a 3D scan of their teeth and gums (scan 1) – both these procedures will be undertaken by a trained dentist (the study Dentist). The 3D scan of your teeth and gums is performed using a handheld scanner. The scanning device looks like a large wand that the dentist will hold and move around the inside of your mouth to scan each surface of your teeth and gums. As the scan is captured, a colour image will appear on a computer screen attached to the scanner. Once a full scan of your mouth has been captured, it will then be saved using a unique study number that has been assigned to you.

You will then be randomised (a similar process to flipping a coin) into either the Control group or Test group (heads or tails)

If you are allocated to the control group the study procedure will be as follows:

- The dentist will use a standard vegetable dye to stain your dental plaque pink, the stain is easily removed by tooth brushing.
- The dentist will assess the amount of dental plaque you have on your teeth using a standard dental technique.
- The dentist will then take a second 3D scan of your mouth (scan 2) to record this.

- You will then be given instruction about how to clean your teeth and gums in the same way as any dentist in dental practice would.
- You will then be asked to brush your teeth following the guidance that you have just been given
- The dentist will then assess your teeth again and record any dental plaque remaining
- The dentist will then take a final 3D scan (scan 3).
- At the end of the visit, you will be given an appointment for Visit 3.
- Between study visits you will be asked to continue with your normal oral hygiene regime using the toothpaste and toothbrush that you normally use.

If you are allocated to the test group the study procedure will be as follows. Items in blue will only be undertaken in this group

- The dentist will use a standard vegetable dye to stain your dental plaque pink, the stain is easily removed tooth brushing.
- The dentist will assess the amount of dental plaque you have on your teeth using a standard dental technique.
- The dentist will then take a second 3D scan of your mouth (scan 2) to record this.
- You will be shown scans 1 and 2 of your teeth and using these it will be explained to you which areas you need to focus on when you clean your teeth and gums and how to do this the best way possible.
- You will be given a gum healthcare toothpaste to use throughout the study.
- You will then be asked to brush your teeth following the guidance that you have just been given
- The dentist will then assess your teeth again and record any dental plaque remaining
- The dentist will then take a final 3D scan (scan 3).
- You will be shown the 'after toothbrushing' scan (scan 3) so you can see how well you have managed to clean your teeth and if necessary, you will be given you some more advice.
- You will be emailed copies of your scans to remind you which areas of your mouth you need to concentrate on when cleaning. Please note, if you do not have an email address, we will provide you with paper copies of your scans.
- At the end of the visit, you will be given an appointment for Appointment 2.
- Between study visits
    - You will be asked to brush twice daily with the toothpaste provided, your normal toothbrush and the oral hygiene guidance that you have received
    - you will also be sent follow up texts to remind you about your toothbrushing routine.

Visit 2, 3 and 4

Appointments 2, 3 and 4 will take place at the following time points following the baseline visit (visit 2)

- Visit 2 will take place 3 weeks after visit 1
- Visit 3 will take place 3 months after visit 1
- Visit 4 (the final visit) will take place 6 months after visit 1.

These visits will follow the same pattern as visit 1 – Part B and you will stay in the group that you were put in at visit 1 until the end of visit 4.

At the end of visit 4:

If you are in the control group, you will now be given your scans from the study and using these, the study dentist will show you the areas in their mouth that you should focus on when you are cleaning your teeth and explain how to clean these in the best way possible.

If you are in the test group, you will be asked to return any toothpaste that you have not used.

Expenses and payment

In recognition of the time commitment in taking part in the study, you will receive up to £150.

You will receive the following payments for completing each visit:

- Visit 1 Part A – Screening– £10.
- Visit 1 Part B – Baseline - £15.
- Visit 2 – 3-week appointment - £25.
- Visit 3 – 3-month appointment -£50.

And finally

- Visit 4 – 6-month appointment - £50.

The amount you receive will depend on the number of visits you complete, and payments will be made in instalments as detailed below.

- Payment 1 – after visit 2 – up to £50, depending on how many visits you have attended.
- Payment 2 – after visit 3 - £50.
- Payment 3 – after visit 4 - £50.

What are the products I will be provided with?

If you are in the test group, you will be provided with a toothpaste to use for the duration of the study to use with your normal preferred toothbrush. This toothpaste has been chosen as it is product that is on sale in shops in the UK and is known to help improve gum health as it contains sodium bicarbonate.

If you are in the control group, you will not receive any study products. Instead, you will be asked to continue using your normal preferred toothpaste and toothbrush.

What are the possible risks or side effects of taking part?

You are not expected to experience any risks or side effects from taking part in the study. All procedures and assessments will be carried out by appropriately trained personnel. The 3D scanner is routinely used in dentistry. Only standard examining procedures and sterile oral examination instruments will be used.

If you enrol on the study and experience a side effect please use the contact details on this information sheet to alert the study team who will ask you to visit the study site for an assessment if necessary.

Are there any benefits in taking part?

You will be given personalised oral hygiene advice and instructions on improving your gum health. You will also have helped the dental profession and dental researchers gain a better understanding of whether 3D images are useful for improving patient tooth cleaning routines and tooth and gum health.

What will happen if I do not want to carry on with the study?

You are free to withdraw from the study at any time without giving a reason.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Further detailed information on this can be found in Part 2.

Contact details.

If you have any further questions concerning the study, or in case of any difficulty during the study please contact:

Primary Contact	Secondary Contact
Prof. Nicola West Principal Investigator Clinical Trials Unit School of Oral & Dental Science Bristol Dental School & Hospital Lower Maudlin Street Bristol BS1 2LY Tel: 0117 342 9638	Nikki Hellin Study Co-ordinator Clinical Trials Unit School of Oral & Dental Science Bristol Dental School & Hospital Lower Maudlin Street Bristol BS1 2LY Tel: 07773 579130 nikki.hellin@bristol.ac.uk

24-hour Emergency contact number: 07773 579130

If the information you have read in Part 1 has interested you, and you are considering participation, please continue to read the additional information in Part 2 before making a final decision.

PART 2

What happens if something goes wrong?

In the unlikely event that you are harmed because of this study, there are no specific compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Please note it is advisable for people with private healthcare insurance to inform their insurers about participation in research studies. This study will be sponsored by the University of Bristol. The University has Public Liability insurance to cover the liability of the University to research participants.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this clinical study, please contact Professor Nicola West on 0117 342 9638 or the Research Governance Team, University of Bristol, (researchgovernance@bristol.ac.uk).

Will my taking part in this study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential.

Bristol University is the sponsor for this study. We will be using information from you in order to undertake this study and Bristol University will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Bristol University will keep identifiable information about you for 3 years after the study has finished.

How will we use information about you?

We will need to use information from you for this research project. This information will include your initials/ name/ contact details and age. People will use this information to do

the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Your scans will be held on University of Bristol secure, password protected electronic storage. The scans only show your teeth and gums and will be identified by a code, not your name. During the study only study team members will have access to your scans. The scans will not be provided to GSK.

With your consent after the study reports have been published we will deposit your anonymous data and scans in a secure University of Bristol repository so that it can be shared with other bona fide researchers whose projects will be reviewed and approved by a University data access committee. Also, if you agree, your anonymised scans will be used for training other dental care professionals.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, your data saved from this study may be used for future research.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At http://www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- by asking one of the research team
- by sending an email to data-protection@bristol.ac.uk , or
- by calling the University's Data Protection Officer on (0117) 3941824.

What will happen to the results of the research study?

It is possible that the results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymised as detailed in 'Confidentiality' above. The protocol summary may be posted on a publicly available protocol register. When the study has been completed If you would like to find out

the results of this study please contact the clinical trials unit team using the contact details above.

Who has reviewed the study?

All research is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given a favourable opinion by the East of Scotland NHS Research Ethics Committee.

Who is responsible for the study?

The Study is being sponsored and managed by the University of Bristol. The study is being funded by GlaxoSmithKline Consumer Healthcare.

Intellectual property statement

The information and any materials or items that you are given about or during the study (such as information regarding the study drug(s) or the type of study being performed) should be considered the confidential business information of the study sponsor. You are, of course, free to discuss with your friends and family while considering whether to participate in this study or at any time when discussing your present or future healthcare.

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.