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## **RESEARCH PARTICIPANT INFORMATION SHEET**

### **A pilot study to evaluate the diagnostic accuracy of intraoral scan-derived visual features in detecting gingival inflammation using bleeding on probing as a reference**

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?**

With the increased use of technology in dentistry, there is more scope to be able to record accurate 3D images of the mouth which can be used by oral healthcare professionals as aids in assessment and monitoring of oral health and disease using non-invasive methods.

3D scanning with increased accuracy and resolution, means it is now possible to capture images of your teeth and gums in detail. These scans are time efficient, easy to record and can be kept for future reference. They are already widely used in dentistry to make dental implant retained dentures and to monitor orthodontic treatment and can position teeth with high accuracy.

The aim of this study is to investigate how accurate these 3D images are in being able to assess gum health and disease across a range of gum colourings. This will be done by comparing visual gum features on a scan to the scores recorded from a visual assessment of your gum health.

This study is being sponsored by University of Bristol and funded by 3Shape TRIOS A/S. It is being carried out by the Dental Clinical Trials Unit at Bristol Dental Hospital under the University of Bristol. The study has been approved by University of Bristol WS1 Ethics Committee. 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. Anyone aged 18 or over who satisfy the criteria below can 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 change your mind, you are free to stop your participation in the study at any time without giving a reason.

You are eligible to take part in this study if you;

- Are willing and able to give informed consent for participation in the study
- Of any gender aged 18 years or above
- In good general health
- Able and willing to undergo all study procedures
- Have a minimum of 10 natural teeth
- Have no oral lesions or conditions
- Have no systemic disease/ medication affecting the gums
- Are a non-smoker
- Have both non-inflamed gums/minimally inflamed gums that are visible on simple visual examination

You will be excluded from the study if you;

- Currently participating in any other cosmetic trials or any clinical trials
- Have obvious signs of untreated decay
- Are undergoing orthodontic treatment
- You have undergone depigmenting treatment (change the colour of your gum tissue)
- You are an immediate employee of the sponsor or the research team conducting the study

### **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 1 study visit. It is anticipated that the visit will last approximately 45 minutes. All clinical assessments will be performed by the University Dental Clinical Trials Unit (CTU) Research Dentist. Appointments will be conducted at The Bristol Dental Hospital.

### **Study Visit**

#### **Visit 1:**

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 be taking - this will be recorded in your study notes for the purposes of the study team only.

You will then have an oral assessment to determine you are eligible for this study. The study dentist will then start the assessments. They will look at your gums and assess the colour of your gums by just using a dental mirror. After this, you will have your mouth 3D scanned. The study dentist will then assess your gum thickness around each tooth by using a dental probe to gently touch the gum line area around the teeth. The study dentist will then assess the number of bleeding points in your mouth. They will do this by air drying your gum area and using the same dental probe to gently touch the gum line area around the teeth. You may feel some discomfort during these tests. If the discomfort is too great, you can ask the dentist to stop the assessments at any time.

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. The scans themselves may each take about 5 minutes of the overall appointment time.

#### **Expenses and reimbursement**

In recognition of the time commitment in taking part in the study, you will receive £50. If you fail to meet the inclusion and exclusion criteria at the screening stage and can not continue on the study or if you withdraw part way through the study, you will be reimbursed £10 for your time and to cover any costs incurred from travel or parking to attend this visit.

#### **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. You might experience very mild, temporary discomfort from the intraoral scan. You may feel distress from sitting in a dental chair and having your teeth examined.

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 have helped the dental profession and dental researchers gain a better understanding of the accuracy of the scanner in picking up a range of gum colours and detecting gum health and diseases.

#### **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. You can let a member of the study team know. No new information will be collected or processed.

#### **Contact details**

If you have any further questions concerning the study, or in case of any difficulty during the study please contact the Principle Investigator or the secondary contacts of the study team. Details of which can be found on the following page:

<b>Primary Contact</b>	<b>Secondary Contact</b>
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	Del Buck/Nikki Hellin Study Dental Nurse/Study Co-ordinator Clinical Trials Unit School of Oral & Dental Science Bristol Dental School & Hospital Lower Maudlin Street Bristol BS1 2LY Tel: 07827956855 del.buck@bristol.ac.uk nikki.hellin@bristol.ac.uk

**24-hour Emergency contact number: 07827956855**

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. This study will be funded by 3Shape TRIOS A/S, Copenhagen, Denmark.

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, ([research-governance@bristol.ac.uk](mailto:research-governance@bristol.ac.uk)).

### **Will my taking part in this study be kept confidential?**

YES. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you will have your name removed so that you cannot be recognised. During the study, all data recorded will be recorded against your participant number. Your participation in the study will be treated as confidential, that is, any personally identifiable information recorded, for example the signed consent form, will be held and processed under secure conditions only at the Clinical Trials Unit at the Bristol Dental School. The study information will be stored securely

by the Bristol Dental School Clinical Trials Unit and will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. The University of Bristol Dental Clinical Trials Unit will collect information from you for this research study in accordance with our instructions and will adhere to GDPR regulations 2018. The University of Bristol Data Protection officer is Henry Stuart.

The Dental Clinical Trials Unit will keep your name and contact details confidential and will not pass this information to the University of Bristol. The Dental Clinical Trials Unit will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from the University of Bristol may look at your personal information, medical and research records to check the accuracy of the research study. The University of Bristol will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

Your scans will be held on 3Shape's secure, password-protected electronic storage. The scans only show your teeth and gums and will be identified by a code, not your name. They will be stored for 10 years.

#### **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 <https://www.bristol.ac.uk/secretary/data-protection/privacy-notice/research-participant-privacy-notice/>
- by asking one of the research team
- by sending an email to [data-protection@bristol.ac.uk](mailto: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 and results may be posted on a publicly available protocol register such as [www.ISRCTN.com](http://www.ISRCTN.com). This will not include information that can identify you.

If you would like to find out the results of this study directly, 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 University of Bristol (WS1) Research Ethics Committee.

**Who is responsible for the study?**

University of Bristol is the sponsor and 3Shape is funder for this study.

**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.