NIHR HTA REFLECT TRIAL

PATIENT INFORMATION LEAFLET

A **R**andomised controlled trial to **E**valuate the effectiveness and cost benefit of prescribing high dose **FL**uoride toothpaste in preventing and treating d**E**ntal **C**aries in high-risk older adul**T**s

IRAS Number 233335

INVITATION TO TAKE PART

We would like to invite you to take part in a research study related to dental caries (tooth decay) in older adults. REFLECT is a research study looking at how effective high dose fluoride toothpaste is at preventing and treating tooth decay in older adults. The study will run for 3 years and aims to recruit around 1200 participants from dental practices across the UK.

Before you decide if you would like to take part it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Feel free to talk to you dentist or other people about taking part in the study if you wish. Ask your dentist if there is anything that is not clear or if you would like more information.

BACKGROUND TO THE CONDITION

Recent research has found that many more people are keeping their own teeth for longer. Although this is a good thing it also means that when people begin to suffer with decay, the treatments required are more complex and expensive and may be very costly. There is a need to help people keep their own teeth free from decay as long as possible.

Since the 1970's fluoride toothpaste has been widely used to prevent tooth decay. Standard fluoride toothpaste, available to buy on the high street, contains around 1400 parts per million (ppm) of fluoride. High dose fluoride toothpaste, containing 5000ppm fluoride, is available by prescription from your dentist. It is increasingly provided to patients judged to be at risk of decay. In 2016 prescriptions of high dose fluoride toothpaste cost the NHS over £20 million and these costs are increasing rapidly. However, there is a lack of evidence to demonstrate that this toothpaste benefits patients and is cost-effective for the NHS.

WHAT IS THE PURPOSE OF THE STUDY?

We want to compare the costs and benefits of regular toothpaste bought over the counter with the high dose fluoride toothpaste prescribed by dentists to patients over 50 years old who have been judged to be at risk of developing tooth decay. We want to see if prescribing the toothpaste can improve the dental health of this group of patients and reduces the cost of dental treatment for both patients and the NHS.

WHY HAVE I BEEN CHOSEN?

Your dental practice has agreed to work with us and we would like to invite you to consider taking part in this research project. The research concentrates on preventing tooth decay in adults aged over 50 years and at risk of developing decay, so only patients who are judged by their dentist to be at risk of tooth decay will be invited to join the study. Your dentist will assess your decay risk at your next checkup.

WHO IS ELIGIBLE TO TAKE PART?

If you are aged 50 and over, receiving all or part of your dental care through the NHS and are at risk of tooth decay or have already been diagnosed as having tooth decay, you may be eligible to take part in the study. Your dentist will decide if they think you are eligible and if high dose fluoride toothpaste is appropriate for you.

If you are currently prescribed high dose fluoride toothpaste or if you are sensitive to Sodium Fluoride or the other ingredients in high dose fluoride toothpaste, you will not be able to take part. If you are living in the same household as someone already taking part in REFLECT you will also not be able to take part. You must also be able to provide informed consent.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not you take part. Please take as much time as you need to make this decision. Taking part in this study is voluntary and you are free to withdraw at any time, even after you have provided your consent to take part.

Deciding not to take part in the study will not affect your eligibility for NHS dental treatment in any way and your decision will not affect the standard of care you receive now or in the future. You can read this information leaflet as many times as you wish and ask your dentist as many questions as you like about the study.

WHAT WOULD TAKING PART INVOLVE?

How we will take your consent

At your next check up your dentist will give you a dental examination as usual and decide if you are at risk of developing decay. If he or she decides that you are at risk, you will be invited to take part in the study and your dentist will explain what it entails and answer any questions you have about the study. If you decide to participate you will be asked to sign a consent form to be part of the study. The consent form will ask you to provide consent for us to access your clinical records and information held on national NHS data sets about the dental treatment and dental prescriptions you have received during your involvement with the trial. You will also have the option to consent to being contacted in the future for long-term follow-up and participating in other dental research, but we will only do this with your permission.

What happens next?

If you decide to participate in the study you will be randomly allocated (chosen by computer with an equal chance of joining) to one of two groups. Half of the people taking part will be in a group that will be prescribed the high dose fluoride toothpaste and advice on how to use this by their dentist and the other half will be in a group that will receive advice from their dentist on buying and using standard fluoride toothpaste, both you and your dentist will know to which group you have been allocated. If you choose to take part in the study you will be followed up for 3 years. At the end of the study we will compare the dental health and the costs of dental care of the two groups. Your dentist will ask you to attend for your routine checkups in the usual way and you should attend outside of these scheduled appointments as usual if you experience any problems.

How you will be followed up

At the first visit an independent dentist employed by the trial, from outside your dental practice, who doesn't know what group you have been allocated to, will examine your teeth and gums to record information about your dental health. This initial examination will take place at the same visit as your routine dental checkup. Three years after you join the study your teeth and gums will be examined by an independent dentist employed by the trial again during the same visit for your routine dental checkup.

At the first visit you will also be asked to complete a confidential questionnaire asking about your general and oral health, your attitudes and beliefs towards tooth brushing, sugar consumption and how much it costs you to attend the dentist.

No matter what group you are in, you will be asked you to complete a short questionnaire each time you attend the dentist. This will collect information on the costs of attending the dentist and if you have experienced any dental or other health problems since your last visit. In addition we will post a questionnaire each year to your home address to collect information on your tooth brushing and sugar consumption and your views on oral health. We will provide a FREEPOST envelope for return of the annual questionnaires to the REFLECT Study Office, a reminder letter may also be sent if we don't hear back from you. It is estimated that each questionnaire will take approximately 15 minutes to complete but you can take as long as you need.

We realise completing the questionnaire will take a little time and to recognise this we will provide all participants a £25 gift voucher at the start of the trial and another £25 voucher at the end to thank you your support.

If decay starts in your teeth you will receive routine dental treatment, such as fillings, as advised by your dentist as normal.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will receive the same health care from your dentist whether or not you choose to participate in the study. You may not benefit personally from taking part. By taking part, however, you will be directly helping us to inform the treatment of future patients at risk of developing tooth decay. The results of the study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ANY TREATMENT RECEIVED WHEN TAKING PART?

The high dose fluoride toothpaste is safe if you follow the instructions given by dentists and on the packaging. The toothpaste, like standard toothpaste, needs to be stored out of the reach of young children. On rare occasions (less than 1 in 1000 people treated), use of the toothpaste has resulted in allergic reactions e.g. rash, itching swelling and redness; and a burning sensation in the mouth has also been reported. If these symptoms occur, or any other symptoms that you feel could due to the toothpaste, you should contact your dentist who will assess the situation and take appropriate action, which may include stopping using the toothpaste.

Manchester University NHS Foundation Trust is the sponsor of the trial and has overall responsibility for the safety of patients involved in the trial. The Trust has insurance cover for no fault compensation for bodily injury, mental injury or death where the injury resulted from a trial or procedure received as part of the trial. This would be subject to policy terms and conditions. Any payment would be without legal commitment. (Please contact the Patient Advice and Liaison Service (PALS) Tel: 0161 276 8686, Email: pals@mft.nhs.uk for more information on this). The Trust would not be bound to pay this compensation where the injury resulted from a drug or procedure outside the trial protocol or if the protocol was not followed.

In the unlikely event that something goes wrong and you are harmed as a result of someone's negligence then you may have grounds for a legal action to seek compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

An independent committee will monitor the health of patients in each group and record and assess any serious adverse events that arise, and will stop the study early if they think there is any risk to patients participating in the study**.**

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Your dentist will continue to provide your dental care after the study has ended. Your future dental care and provision of fluoride toothpaste will be at the discretion of your own dentist. You will be able to access the results of the study once they are published and we will provide you with details about how to access this information.

If for any reason the study ends earlier than expected, we will let you know and your continuing care will carry on as normal.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. High dose fluoride toothpaste is already being used in the NHS to treat tooth decay. Your participation is only to help us evaluate how effective this is and should not involve any additional risk to you.

If you decide to take part but then have subsequent concerns about any aspect of this study, you should ask to speak to your dentist in the first instance, who will put you in touch with one of the senior clinicians conducting the study and we will do their best to address any concerns. If we are unable to resolve your concerns or you wish to make a complaint regarding the study, you will be directed to the appropriate person in Manchester University NHS Foundation Trust with responsibility for dealing with complaints in relation to clinical trials.

If you should be unable or unwilling to continue in the REFLECT trial we will withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the annual questionnaires. We will tell your GP you are taking part, but only with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsor(s), the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential, and will be held securely in accordance with the Data Protection Act 1998. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

In this study, we will collect relevant data (e.g. Fluoride toothpaste prescription information) from the NHS central registers. The reason for this is to make sure that we have the correct information about all the participants taking part in this study and ensure that the results are as accurate as possible.

Other researchers may wish to access data from this study in the future. If this happens it will not be possible to identify participants from the stored data because it will not include names, addresses or dates of birth. The consultant leading the study will ensure that any other researchers wishing to use the data comply with legal, data protection and ethical requirements.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the REFLECT Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can decide at any time not to carry on with this study, but you should continue attending appointments with your dentist as part of your standard care.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with a risk of developing tooth decay. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE STUDY?

This study is sponsored by the Manchester University NHS Foundation Trust which has overall responsibility for the management of the study. The study is funded by the National Institute for Health Research Health technology Assessment Programme (NIHR HTA). The research is being carried out by a group of experienced clinicians and researchers from the University of Manchester, University of Dundee, the Health and Social Care Board of Northern Ireland and the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee (REC) to protect your interests. This study has been reviewed and approved by North East - Newcastle & North Tyneside 1 Research Ethics Committee, and the Medicines and Healthcare products Regulatory Agency, which is the government agency which looks after medicines research.

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the REFLECT Study. Please ask us if you have questions or would like more information about the study.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

REFLECT Study Office Dundee Dundee Dental School and Hospital University of Dundee Park Place Dundee DD1 4HN Tel: 01382 381213 Email: reflect@dundee.ac.uk Web: https://w3.abdn.ac.uk/hsru/REFLECT/	Other Trial Contacts: Trial Chief Investigator and England Lead: Professor Martin Tickle Scotland Lead: Professor Jan Clarkson Northern Ireland Lead: Michael Donaldson

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