

Project document 3– Older Cohort Participant Information Sheet

Water Fluoridation Study – Parent’s Information Sheet 5 year old cohort

Dear Parent or Guardian

I am writing to you to ask for your consent (agreement) for your child to be involved in a research study that we are conducting in conjunction with Cumbria Partnership NHS Foundation Trust. Before you can decide if you wish for your child to take part, I would like to give you some more information about the background to the study.

Tooth Decay

Dental decay, is still a major problem within the UK. A number of measures have reduced the amount of decay within certain parts of the population and the most important of these are fluoride in both water supplies and toothpaste. Dental decay often requires a visit to the dentist and the placement of a filling. This will often mean time off school and work for both child and parent. Untreated dental decay can lead to painful toothache which may ultimately require a tooth to be extracted.

Water fluoridation

Many areas of the UK still do not benefit from water fluoridation. Recent changes in the law will enable more local determination to implement water fluoridation if they choose. Water fluoridation is being reintroduced into certain areas of Cumbria. We are interested in following the effects of this introduction alongside an area that is not receiving water fluoridation to assess the benefits.

Why is my child being asked to participate?

We are running this study in two areas, one in West Cumbria (fluoridated water), the other in North Cumbria (non - fluoridated water). By looking at these different areas we will be able to see the differences that water fluoridation makes to the oral health of the children living in these regions. Your child has not been individually selected – we are asking the parents or guardians of all children who are in their first year of school within these areas if they would like to participate with assessments taking place when your child is 5, 7 and 11 years old. Your child will be part of a group of approximately 3200 we aim to assess. Participation in this study is entirely voluntary. You or your child may choose to withdraw from the study at any time and you do not have to give us a reason. We will ask you at each exam (5 , 7 and 11) whether you still wish to participate. If you do not you can return an opt out form meaning your child will no longer participate in the study. We will also give you the option to have your previous information removed from the data set.

What will happen to my child if they participate in the study?

If you, and your child, agree to take part in the study they will be contacted at school. We will do a number of different examinations. The first will be a very standard dental check up where a dentist will look at all of your child’s teeth. Next, a few pictures will be taken. These will be done with a very small camera in the mouth. It will be necessary to dry the teeth using some cotton wool. None of the photographs will show your child’s face – they will only be of their teeth. We would expect that all of the examinations will take no more than 10 minutes. All of the examinations are done without any probing of the teeth; just with either a mirror or a camera and are completely painless. After this your child will go back to their classroom. We will look at the images taken after the study has finished.

Where will all these photographs be kept and who has access to them?

We will store all the photographs and clinical information on computers that are secured with a password. None of the information that we collect will have your child’s personal details on, i.e. the

information will be pseudonymised (where you will be given a unique identifier and identifiable information will be kept separate). The only people to have access to the information are the scientists involved in the study. We hope to publish our results in a scientific journal. No information concerning your child will be included. We will provide a copy of the results to your child's school if you would like to see them. The study may be monitored by external bodies such as the ethics committee or regulatory authorities. Once again, your child will not be identified during this process.

What if my child has something wrong with their teeth?

If the examining dentist notices something in your child's mouth that they feel needs treating they will write to you and let you know. You can take this letter to a dentist and they will be able to advise you further.

What benefit is there to me or my child?

This study aims to understand better the link between the reduction in tooth decay and water fluoridation. You and your child will be helping us to develop more information on this important issue. Your child may not gain a direct benefit by taking part in this study but they will receive a full dental examination and this may help identify any problems that they have. Once your child has taken part they will be given a sticker to thank them for their help.

What risks are there to my child taking part?

There are no risks to your child taking part in this study. All of the procedures and equipment being used have a safe history of use and have been used in studies before. In the unlikely event that something does go wrong and your child is harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or Cumbria Partnership NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who is paying for this study?

The University of Manchester is the study sponsor and the funding is sourced from the National Institute for Health Research.

Who has reviewed this study?

This research has been looked at by an independent group of people called a Research Ethics Committee (REC) to protect the safety, wellbeing, rights and dignity of you and your child. This study has been reviewed and given a favourable opinion by the NHS REC.

Who is running this study, what if I have a question?

The study is being undertaken by researchers at the Universities of Manchester. Professor Iain Pretty is the principle investigator, you will find his contact details at the end of this letter. If you have any questions regarding the study please feel free to contact Michaela Goodwin. You can contact her by email (michaela.goodwin@manchester.ac.uk) or by telephone (0161 2324711).

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

What do I do now?

Please complete the consent form that is attached to this letter. This is very important, even if you do not wish your child to take part. It would be very helpful to us if you could send the form back in the stamped address envelope. Please also complete the questionnaire attached, this is to record other factors, which may have an effect on our final outcome and is important for us to record in the process of examining your child. If you are happy for your child to continue to take part we will ask your child again

on the day if they are happy to have a dentist look at their teeth if they do not want this to happen they will not have to take part.

I would like to thank you for reading this information sheet and considering your child's inclusion in the study. Do please contact Michaela Goodwin if you need any more information.

Yours Sincerely



Dr Iain Pretty



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