ELVIS Kids: Participant Information Sheet

Study Title: The Edinburgh and Lothian Virus Intervention Study for Kids (ELVIS Kids): A randomised controlled trial of hypertonic saline nose drops in children with upper respiratory tract infections.

You are being invited to take part in a research study. Before you decide whether or not 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. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
Upper respiratory tract infection (URTI), otherwise called the "Common cold" can be caused by many different viruses. On average children have 6-12 colds in a year. Most of the time the symptoms are mild. However serious infections such as pneumonia, bronchiolitis and worsening of illnesses such as asthma and chronic obstructive pulmonary disease can all begin with a common cold in which case you may have to see the GP or go to the hospital.

This study is looking at a low-cost intervention (salt-water nose drops) that adults can prepare and use on their child at home. We are doing this study because of promising results in a similar study in adults. From this study, we know that by rinsing the nose and throat with salt water the cold didn't last as long, less over-the-counter medicines were needed and that it was less likely the cold was passed to other family members.

Why have I been asked to take part?
You have been asked to take part as you are the parent / guardian of a child aged 7 years or under and have responded to an advertisement about this study.

Can my child take part?
The research nurse will ask some questions to find out if your child is already on antibiotics, has a known long-term health condition, is known to be immunosuppressed or is already taking part in another study. If your child has had the "nasal Flu vaccine" within two weeks (usually given in school or by the GP), your child cannot take part in the study for this episode of the cold and you will need to wait for the next cold. The nurse will then inform you if your child can take part in the study.

Does my child have to take part?
No, it is up to you to decide whether or not your child should take part in the study. If you do decide you are happy for your child to take part, you will be given this information sheet to keep and be asked to sign a consent form. You will be asked for your consent for members of the study team to review your child's medical record, if needed, to collect data on visits to hospital, and treatment received and to check whether they are suitable to take part in the study. You are still free to withdraw your child from the study at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that your child receives.

Appointment with the Research Nurse
If you agree to take part, we would invite you to an appointment with the research nurse at the **University Hospital Wishaw** to receive information about the study and to give you everything you need to take part. It is not essential your child comes along to the appointment

with you. We will ask for your child's name and date of birth in order to make this appointment. This should take around one hour. As your child's parent / guardian, you will be asked to sign a consent form. Your participation is voluntary, and you are free to withdraw from the study at any time. Your contact details will be collected so the study team are able to get in touch with you.

The research nurse will then use a computer to randomly (i.e. by chance) give your child one of the following two treatments:

1. Control Arm: No 'extra' treatment – just whatever is normally given for a cold.
2. Intervention Arm: Normal treatment plus salt water nose drops at least 4 times per day.

If your child is *well* right now, you will be taught to identify a cold, how to contact the research nurse when your child gets a cold, how to collect nose swabs, how to measure temperature if you feel your child has a fever, how to complete daily diaries and when to complete the end of illness diary. If your child is the intervention arm, you will also be taught how to apply the nose drops.

If your child is *unwell* with a cold right now, you will be taught how to collect nose swabs, how to measure temperature if you feel your child has a fever, how to complete daily diaries and when to complete the end of study diary. If your child is the intervention arm, you will also be taught how to apply nose drops.

How to identify a cold for this study

For this study we would think your child has a cold when we see at least two of the cold symptoms listed: stuffy nose, runny nose, cough, sore throat, or sneezing.

OR

One of the cold symptoms + at least one symptom affecting the whole body:
very tired/no energy, sore muscles, sore head, a high temperature (i.e. fever of 38^0C or over).

When you spot these symptoms, you should log into the online system as soon as possible to answer some questions to check if you should start the trial. If you don't have internet access you should call the research nurse before starting (ideally the same day, but up to 2 days of the cold starting is fine).

Collecting nose swabs

You will be provided with information about how to collect a nose swab from your child. The tubes should be kept in the fridge until you are ready to post them back to us. The swab is designed so that the whole swab cannot be inserted into the nostril by accident and to collect a sample from the correct part of the nose. This makes it very easy to use. There are two sizes of swabs, one for a child younger than 2 years of age and another for older children and adults. You will be given the right one for your child.

You will be asked to collect a nose swab first thing in the morning until your child is well or fora maximum of 5 days. This should be before giving any nose drops if you are in the group using them. You will be provided a box to keep the swabs in and a pre-paid padded envelope to post them to the Virology laboratory. The swabs will be tested to identify which virus has caused your child's illness and the amount of virus present on the swab. We may need to test the samples to see if they contain human DNA that will tell us if the swab was done correctly. We will not do any other genetic tests as part of this study. The samples may be used to detect different bacteria / viruses or for other genetic tests in ethically approved studies in the future. Genetic data is considered to be personally identifiable and we will seek your explicit permission for its potential use in future studies.

If your child is unwell at the point of taking part, you will be asked to collect a nose swab on the same day. If your child is well now, then you will be asked not to collect a swab until you have had confirmation from the online system or nurse that you can start the trial.

Completing daily diary
You will also be asked to keep an online daily diary around the same time every day until you record that your child is not unwell. The longest we would ask you to do the diary would be 28 days if your child continues to feel unwell for longer than this. If the diaries are not completed, we will contact you as a reminder. If you don't have access to the internet we can provide you with paper diaries instead with instructions on how to post these to study nurse.

Preparing and applying nose drops (Intervention arm only)
You will be provided with information, so you know how to safely prepare and apply the nose drops to your child. You will be given sea-salt, a small measuring spoon and 2 jars to make the solution and 2 dropper bottles to give the nose drops. You will also be provided a container, a larger measuring spoon and sterilising fluid to prepare the solution safely if your child is under a year old. Nose drops can be used for up to 24 hours then a new batch should be made. You will be provided labels on which you should note the time and date.

You will need to apply nose drops (3 drops in each nostril) at least 4 times a day. It can be spread out during the day or applied one to three times in the morning, and one to three times in the evening to suit family life. If your child wakes up in the night with symptoms, you can use the nose drops if needed. If you feel your child is unwell and needs more nose drops, you can give them more often. The most we would suggest using them is 12 times in a day (24hours). The drops should be used until the symptoms of the cold are gone or for a maximum of 28 days. The number of times you apply nose drops will need to be recorded in the daily diary.

End of illness diary
When your child is feeling better, we will ask you to complete questions in the "end of illness" diary.

Satisfaction Questionnaire
When your child is feeling better, we will ask you to complete the "satisfaction questionnaire" to see how easy you found the study to do.

Day 28 Question
At the end of the study (day 28), you will receive a text message from the study team to find out if your child developed any wheeze following the cold. You will be requested to answer Yes / No to this message.

What needs to be posted?

1. **Swabs:** After you have taken all the swabs, we ask you to post back the nose swabs as soon as you can in the packaging box and padded envelope provided to the Virology Lab.
2. **Questionnaires:** If you have completed the questionnaires on paper return them by post to the study nurse in the pre-paid envelope provided at the end of the study.

Is there anything I need to do or avoid?
If your child is in the control arm, you should avoid using salt water (saline) nose drops or sprays during the study unless you've been advised to do so by a doctor. If you do, you should record this in the End of Illness Diary.

What are the possible benefits of taking part?
Your child may or may not get a direct benefit from this study. We hope to show, like the study in adults, that salt water nose drops help colds go away more quickly, stop colds from developing into more serious illnesses and make it less likely to spread to other family members but we need to complete this study to see if this is true.

What are the possible disadvantages of taking part?
It is not thought that there are many disadvantages; however, it is possible that you may be inconvenienced by having to come to an appointment at the hospital, maintain the diaries and having to collect nose swabs from days 1-5. Your child may not like having nose swabs taken.

If you are in the intervention arm, you will be asked to make the nose drops every day and apply them at least 4 times a day, which may or may not inconvenience you or your child. Salt sprays have been used safely in children before. Some children using them had a dry, itchy or burning feeling in the nose and some found it had a bitter taste. A small number of children had nose bleeds. Your child may not like having nose drops applied.

It is recommended children and young babies avoid having salt in their diets. It is possible that children may swallow a small amount of salt water as the drops are applied but the amount of salt it contains is so tiny that it will not be harmful.

Please take care that your child does not drink the salt solution from the bottle. However, if by accident your child does drink the salt solution from the bottle, please contact your GP/NHS 24 on 111 for advice.

Tap water can have other bugs that can cause an infection. There is a chance of infection if the nose drop bottle or the solution is not clean or the water is not boiled. We will teach you how to clean the bottles and to safely make the nose drops to help you avoid infections.

If your child is <1 year of age, we will also teach you how to sterilise the containers before preparing the solution to avoid the risk of infection.

We understand that it may be difficult to complete everything required for the study each day whilst caring for an unwell child. If you or your child are unable to complete any part of the study it is ok to continue to take part and record any issues in your daily diary.

What if there are any problems? If you are worried about your child at all and need further medical help, please contact the GP/NHS 24/hospital if you need to. If you need to use other medicines to treat the cold you should go ahead and do this.

If you are worried about any part of this study, please contact Karen Leitch – research Nurse on 07976320284 who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting your local NHS Patient Experience Team. Their contact details can be found at the back of this leaflet.

In the unlikely event that something goes wrong and your child is harmed during the study and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS Lanarkshire but you may have to pay your legal costs. The normal National Health Service complaints process will still be available to you (if appropriate).

What will happen if we don't want to carry on with the study?
If you or your child no longer want to take part, you can stop at any time. There is an option on the online diaries to let us know that you no longer want to takes part and this will let us know not to contact you further.

You can still be part of the study and complete the diaries even if you are no longer able to give the nose drops or take the swabs.
If you do stop, any information and swabs already collected will still be kept by us and used for our study. We would ask that if you no longer want to take part that you post back any nose swabs you have taken if you are still happy for us to use them as part of our study.

What happens when the study is finished?
At the end of your participation in this study, once the study forms have been returned, you will be emailed a £30 Amazon voucher for your inconvenience. We can also pay any reasonable travel expenses for your visit to the hospital.

The data collected will be securely archived for 3 years in case it needs to be reviewed again after the study has finished. The data will then be made anonymous and stored securely by the University of Edinburgh for use in future research if you agree to this. Nose swabs collected from your child will be transferred into the Lothian NRS BioResource if you agree to this. This is a secure place to store samples collected from research and is approved by an Ethics Committee (Ref: 15/ES/0094) to do this. The swabs will only be identified by a lab number and may be used for future studies with the permission of an Ethics Committee. There is no time limit on how long these will be kept and these will be held securely until a request is made to use them in research.

At the end of the research we will analyse the data and publish the results as detailed below.

Will my taking part in the study be kept confidential?
All the information we collect during the study will be kept confidential and there are strict laws that safeguard your child's privacy at every stage. Your child's name will be removed from the data so that they cannot be recognised from it. We will inform your child's GP that they are taking part in this study.

University of Edinburgh and NHS Lothian are the co-sponsors for this study. We will use information from you, your child and your child's medical records in order to undertake this study and will act as the data controller for this study. As a University & NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest to use personally-identifiable information from people who have agreed to take part in research. This is our legal basis when using personal information for research. This means that when you agree to take part in this research study, we will use your child's data in the ways needed to conduct and analyse the research study. Your rights to access, change or move your child's information is limited as we need to manage your child's 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 and your child that we have already obtained, and will continue to process it, for this study only. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Health and social care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research to ensure our research serves the interests of the public.

For further information on the use of personal data by NHS sites, please link to the Health Research Authority (HRA) website; https://www.hra.nhs.uk/information-about-patients/.

If you wish to raise a complaint on how we have handled your or your child's personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not

satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) at https://ico.org.uk/.

Our Data Protection Officer email addresses are;

University of Edinburgh	**NHS Lothian**
Data Protection Officer	Data Protection Officer
dpo@ed.ac.uk	Lothian.DPO@nhs.net

What will happen to the results of the study?
The study will be written up and published in a journal and we will present it at conferences to other doctors. Your child will not be identifiable in any published results. If you would like to know the results of the study, you will be able to find a summary on the study website (www.elviskids.co.uk) once the results are available.

Who is organising and funding the study?
This study has been organised by Dr. Sandeep Ramalingam who is a Consultant Virologist at NHS Lothian with help from the University of Edinburgh. The study is funded by the Chief Scientist Office (CSO).

Who has reviewed the study?
The study has been reviewed by the West of Scotland Research Ethics Committee 03 and was given a favourable ethical opinion. NHS Lothian have also given their approval for the study to take place.

Researcher Contact Details
If you have any further questions, please contact Research Nurse, University Hospital Wishaw. 01698 366151, 07976320284

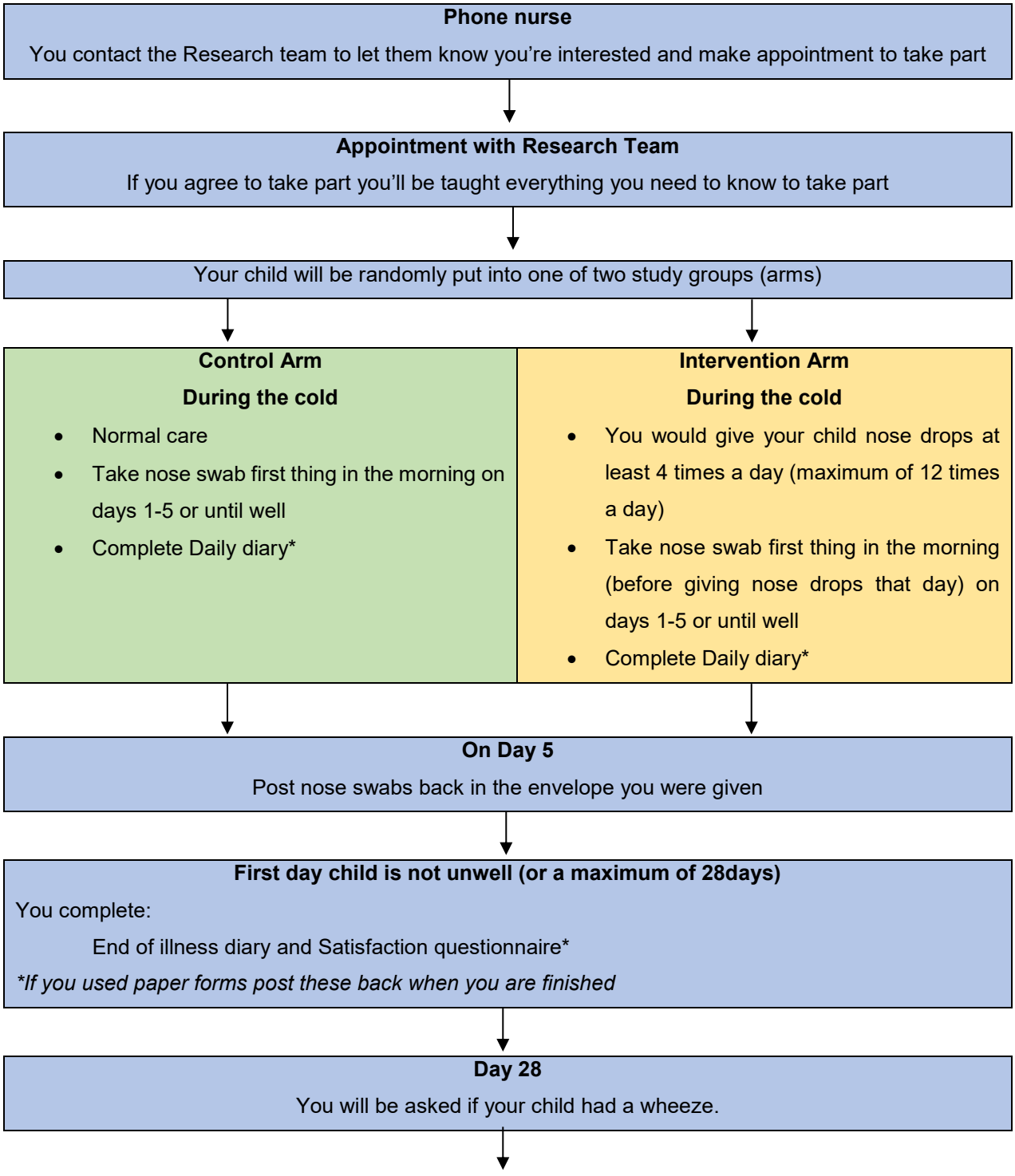
Independent Contact Details
If you would like to discuss with someone independent of the study please contact: Dr. Ingolfur Johannessen, Consultant Virologist, Royal infirmary of Edinburgh, Email: ingo.johannessen@nhslothian.scot.nhs.uk or Phone: 0131 242 6003.

Complaints:
If you wish to make a complaint about the study please contact:
Patient affairs manager, University Hospital Wishaw,
50 Netherton Street
Wishaw
ML2 0DP

Phone: 01698 366 558

Email: Patientaffairs.wishaw@lanarkshire.scot.nhs.uk

Study flow chart



End of study

Once we have received everything back we will send £30 voucher to say thanks!