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ELVIS Kids: Information Sheet for children

Hello, this is ELVIS. He has a Cold!

Elvis does not like a cold.

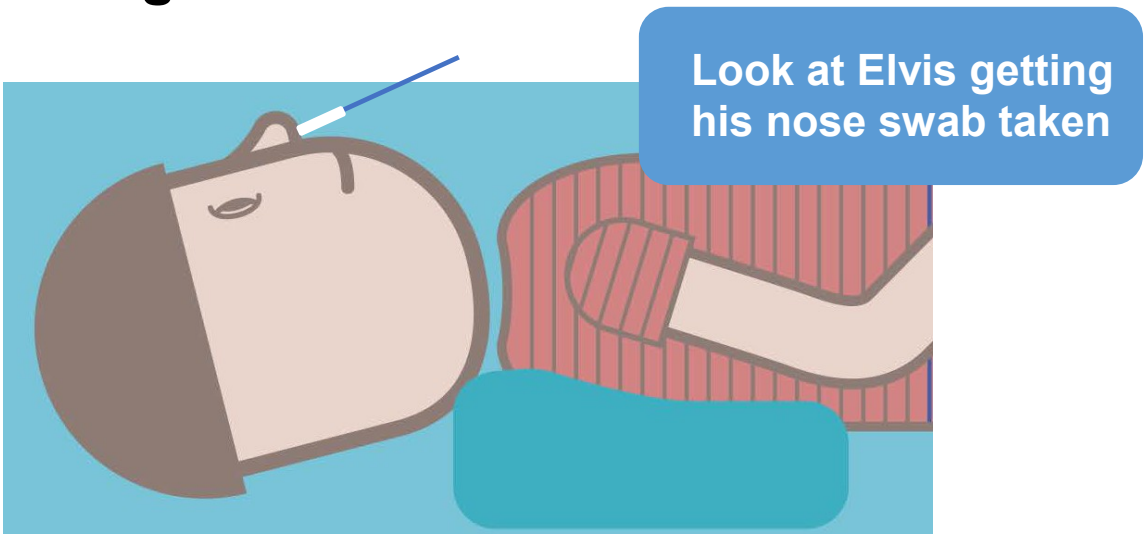
It makes him cough, his nose runs, and he is too tired to play.

He wishes there was a cure for the cold!

So, Elvis goes to meet the nurse in the hospital to take part in a study.

Ramalingam S, *et al. BMJ Open* 2021; 11:e049964. doi: 10.1136/bmjopen-2021-049964

The nurse tells Elvis that he will need to take a swab from his nose for a few days. This is like a cotton bud wiping the inside of his nose. This won't hurt but might tickle a bit!



The nurse tells Elvis that he may be in the group of children that need nose drops for their cold until they are well.

If he is, he will lie down and a few drops of water will be put up his nose by a grown up in his family. This might be tickly or make him want to blow his nose. He will do this every day until his cold gets better.

Ramalingam S, *et al. BMJ Open* 2021; 11:e049964. doi: 10.1136/bmjopen-2021-049964

Not all the children helping with the study will use nose drops. The nurse will look at their computer to see which children will get them.

The nurse tells Elvis that he doesn't have to take part if he doesn't want to and he can change his mind later if he wants. He just needs to tell a grown up.

The nurse thanks Elvis for his interest in the study.

Do you want to be like Elvis and help the nurse too?

What is your name: _____

Colour in this picture of Elvis's Teddy who is visiting the nurse too:

Ramalingam S, *et al. BMJ Open* 2021; 11:e049964. doi: 10.1136/bmjopen-2021-049964

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ELVIS Kids: Assent Form for children

Child to tick all they agree with:	**Participant Number:**	
Do you understand what this study is about?	Yes ☐ No ☐	
Have you asked all the questions you want?	Yes ☐ No ☐	
Have you had your questions answered in a way you understand?	Yes ☐ No ☐	
Are you happy to take part?	Yes ☐ No ☐	

If any answers are 'no' or you don't want to take part, don't sign your name!

If you do want to take part, you can write your name below:

Your name_____

Date_____

The nurse who explained this project to you needs to sign too:

Print Name_____

Sign_____

Date_____

Thank you for your help!

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Participant Number: _____

CONSENT FORM: ELVIS Kids		Please **initial** box
1.	I confirm that I have read and understand the information sheet (Dated: _____ and Version Number_____) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
2.	I understand that my participation and my child's participation is voluntary and that I am free to withdraw at any time without giving any reason and without my child's medical care and/or legal rights being affected.	☐
3.	I give permission for the study team to access my child's medical records 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.	☐
4.	I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals in the study team, from the Sponsor (University of Edinburgh and/or NHS Lothian), from NHS <INSERT TRUST NAME> or other regulatory authorities where it is relevant to my child taking part in this study. I give permission for these individuals to have access to my child's data and/or medical records.	☐
5.	I give permission for my personal information and my child's personal information (including my child's date of birth, and my telephone number and email address) to be passed to the University of Edinburgh for administration of the study.	☐
6.	I understand that the nose swabs collected from my child will be tested to see which bacteria or viruses have caused my child's cold.	☐
7.	I understand that the nose swabs collected from my child may be tested for human DNA to check the samples have been taken correctly.	☐
8.	I agree to my child's anonymised data and nose swabs being kept for use in future ethically approved studies and I understand the samples will be held securely in the Lothian NRS BioResource.	Yes ☐ No ☐
9.	I understand that as part of future ethically approved studies the samples may be tested for human DNA to identify why some children get more infections or why some children have mild and others have severe illness and consent to it.	Yes ☐ No ☐
10.	I agree to my child's General Practitioner being informed of their participation in the study.	☐
11.	I give permission for the trial researchers to contact me by email, phone and text message during the study.	☐
12.	I agree that my child will take part in the above study.	☐

Name of Person Giving Consent		Date		Signature
Name of Person Receiving Consent		Date		Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record

ELVIS Kids Daily Diary (Intervention Arm)

Thanks for your help with ELVIS Kids!

Participant ID: ☐☐☐☐☐

Does my child have a cold?

Your child should have at least two of the cold symptoms listed **OR** one cold symptom and one symptom affecting the whole body to start the study. Please record the symptoms your child has for this cold below.

Cold Symptoms			Whole body Symptoms			
Stuffy nose	O Yes	O No	Fever (≥ 38°C)	O Yes	O No	
Runny nose	O Yes	O No	Low energy/tired	O Yes	O No	
Cough	O Yes	O No	Muscle aches/pains	O Yes	O No	O Don't Know
Sore throat	O Yes	O No	Sore head	O Yes	O No	O Don't Know

When did the illness start?
(Please do not start the study if the cold started more than 48 hours ago)

Date Started: *(DD-MMM-YYYY)* ☐☐-☐☐☐-☐☐☐☐ **Time Started:** *(24 hour clock)* ☐☐:☐☐

If your child's medical details have changed since you first saw the study nurses, please contact the study nurses on STUDY NUMBER before starting the study

Did your child receive the nasal flu vaccine within the last 4 weeks?

O Yes, my child received the nasal flu vaccine O No my child has not received the nasal flu vaccine

If you answered YES, please contact the study nurses on STUDY NUMBER before starting the study

Date Flu Vaccine Received: *(DD-MMM-YYYY)* ☐☐-☐☐☐-☐☐☐☐

Participant ID: ☐☐☐☐☐

Daily Diary: Day 1

Date: ☐☐-☐☐☐-☐☐☐☐ **Time** *(24 hour clock)*: ☐☐:☐☐

Select one option	Not unwell 0	Very mildly 1	2	Mildly 3	Moderately 4	5	Severely 6	7
How unwell is your child today?								

If you ticked 'Not unwell', please skip the next section and go to the 'Other Questions' section

Are these symptoms a problem for your child today? Tick the most appropriate box for each question:

Symptom	No Problem	Minor Problem	Moderate Problem	Major Problem	Don't Know or N/A
Poor appetite					
Not sleeping well					
Irritable, cranky, fussy					
Feels unwell					
Low energy, tired					
Not playing well					
Crying more than usual					
Needing extra care					
Clinginess					
Headache					
Sore throat					
Muscle aches or pains					
Fever					
Cough					
Nasal congestion, runny nose					
Vomiting					
Not interested in what's going on					
Unable to get out of bed					

Other Questions:

How many times did you give the drops in the last day (24 hours)? ☐☐

Were there any side effects? O Yes O No

If yes, please indicate the severity of symptoms by ticking the following where 0 is none and 5 is the worst it can be.

Symptom	None 0	Score 1	2	3	4	Max 5
Runny nose						
Sneezing						
Pain / Sore						
Other symptom 1: _____						
Other symptom 2: _____						
Other symptom 3: _____						

Was a nose swab collected this morning? O Yes O No

If no, what was the reason? O I forgot O My child refused O I had problems doing it
O Other: _____

ELVIS Kids Daily Diary (Control Arm)

Thanks for your help with ELVIS Kids!

Participant ID: ☐☐☐☐☐

Does my child have a cold?

Your child should have at least two of the cold symptoms listed **OR** one cold symptom and one symptom affecting the whole body to start the study. Please record the symptoms your child has for this cold below.

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Runny nose	O Yes	O No	Low energy/tired	O Yes	O No	
Cough	O Yes	O No	Muscle aches/pains	O Yes	O No	O Don't Know
Sore throat	O Yes	O No	Sore head	O Yes	O No	O Don't Know

When did the illness start?

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Participant ID: ☐☐☐☐☐

Daily Diary: Day 1

Date: ☐☐-☐☐☐-☐☐☐☐ **Time** *(24 hour clock)*: ☐☐:☐☐

Select one option	**Not unwell** 0	**Very mildly** 1	2	**Mildly** 3	**Moderately** 4	5	**Severely** 6	7
How unwell is your child today?								

If you ticked 'Not unwell', please skip the next section and go to the 'Other Questions' section

Are these symptoms a problem for your child today? Tick the most appropriate box for each question:

Symptom	No Problem	Minor Problem	Moderate Problem	Major Problem	Don't Know or N/A
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Not sleeping well					
Irritable, cranky, fussy					
Feels unwell					
Low energy, tired					
Not playing well					
Crying more than usual					
Needing extra care					
Clinginess					
Headache					
Sore throat					
Muscle aches or pains					
Fever					
Cough					
Nasal congestion, runny nose					
Vomiting					
Not interested in what's going on					
Unable to get out of bed					

Other Questions:

Was a nose swab collected this morning?	O Yes O No
If no, what was the reason?	O I forgot O My child refused O I had problems doing it O Other: _____

Participant ID: ☐☐☐☐☐

End of Illness Diary *(Intervention Arm)*

END OF ILLNESS DETAILS

Please complete this on the first day your child is well after their cold or after 28 days if your child remains unwell

Date Diary Completed: ☐☐-☐☐☐-☐☐☐☐
(DD-MMM-YYYY)

How many adults and children live in the house (including your child who's taking part in ELVIS Kids)?

Adults ☐☐ Children ☐☐

Did anybody at home develop the cold after your child?

O Yes O No

If yes, how many were adults?

☐☐

If yes, how many were children?

☐☐

How easy was it to apply the nose drops

Very Easy	Easy	Moderate	Difficult	Very Difficult	Did Not

What was your preferred option?

O Cradle child in arms O Lay child on bed O Other: _____

Do you think applying nose drops made a difference to your child's symptoms?

O Yes O No

Would you do it again if your child had a cold in the future?

O Yes O No

If no, what is the reason? (tick all that apply)

No improvement O Yes O No

Too difficult O Yes O No

Child did not like it O Yes O No

There were side effects O Yes O No

Other O Yes O No Other:_____

Ramalingam S, *et al. BMJ Open* 2021; 11:e049964. doi: 10.1136/bmjopen-2021-049964

Participant ID: ☐☐☐☐☐

End of Illness Diary *(Intervention Arm)*

END OF ILLNESS DETAILS *(continued)*

Did your child take over-the-counter medication for their cold?

O Yes O No

If yes, approximately how much did you spend?

£ ☐☐.☐☐

Did you seek further medical attention related to the cold?

O Yes O No

If yes, how many times did you use each of the following?

a. Telephone contact GP? ☐☐

b. Telephone contact out of hours GP? ☐☐

c. Telephone contact NHS 24? ☐☐

d. Attended GP? ☐☐

e. Attended out of hours GP? ☐☐

f. GP Home visit? ☐☐

g. Attended hospital? ☐☐

h. Was your child admitted to hospital?

O Yes O No

If yes, number of days and what was the reason

Number of days: ☐☐ Reason: _____

Does your child attend nursery/school?

O Yes O No

If yes, number of days your child missed nursery/school during this cold

☐☐

Number of days or work missed by adults to take care of your child

☐☐

Has your child had wheezing or whistling in the chest while they had this cold?

O Yes O No

If yes, how many days did your child have wheezing or whistling?

☐☐

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Participant ID: ☐☐☐☐☐

End of Illness Diary *(Control Arm)*

END OF ILLNESS DETAILS

Please complete this on the first day your child is well after their cold or after 28 days if your child remains unwell

Date Diary Completed: *(DD-MMM-YYYY)* ☐☐-☐☐☐-☐☐☐☐

How many adults and children live in the house (including your child who's taking part in ELVIS Kids)?

Adults ☐☐ Children ☐☐

Did anybody at home develop the cold after your child?

O Yes O No

If yes, how many were adults?

☐☐

If yes, how many were children?

☐☐

Did you use salt water nose drops/sprays for your child's cold?

O Yes O No

If yes, what is the name of the drops/sprays you used?

_____

How many days did you use the drops/sprays?

☐☐

How many times per day did you use the drops/sprays?

☐☐

Did your child take over-the-counter medication for their cold?

O Yes O No

If yes, approximately how much did you spend?

£☐☐.☐☐

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Participant ID: ☐☐☐☐☐

End of Illness Diary *(Control Arm)*

END OF ILLNESS DETAILS *(continued)*

Did you seek further medical attention related to the cold?

O Yes O No

If yes, how many times did you use each of the following?

a. Telephone contact GP? ☐☐

b. Telephone contact out of hours GP? ☐☐

c. Telephone contact NHS 24? ☐☐

d. Attended GP? ☐☐

e. Attended out of hours GP? ☐☐

f. GP Home visit? ☐☐

g. Attended hospital? ☐☐

h. Was your child admitted to hospital?

O Yes O No

If yes, number of days and diagnosis

Number of days: ☐☐ Diagnosis: _____

Does your child attend nursery/school?

O Yes O No

If yes, number of days your child missed nursery/school during this cold

☐☐

Number of days or work missed by adults to take care of your child

☐☐

Has your child had wheezing or whistling in their chest while they had this cold?

O Yes O No

If yes, how many days did your child have wheezing or whistling?

☐☐

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Participant ID: ☐☐☐☐☐

Satisfaction Questionnaire

About the Study

Q1. How easy was it to collect the swabs?

Very Easy	Easy	Moderate	Difficult	Very Difficult	Did Not

Q2. How would you rate the comfort level of your child with the swabs?

Very Comfortable	Comfortable	Moderately Comfortable	Uncomfortable	Very Uncomfortable	Did Not

Q3. How easy was it to return samples?

Very Easy	Easy	Moderate	Difficult	Very Difficult	Did Not

Q4. How easy was it to complete the daily diary?

Very Easy	Easy	Moderate	Difficult	Very Difficult	Did Not

Q5. Based on your experience, do you have any suggestions for improving the trial procedures in the future?

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Participant ID: ☐☐☐☐☐

Day 28 Wheeze Details

DAY 28 WHEEZE DETAILS	
Between your child's cold ending and today, did your child develop wheezing or whistling in their chest?	O Yes O No
If yes, how many days did your child have wheezing or whistling? *(Please enter a number, e.g. 4)*	☐☐

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