



The University of  
Nottingham

UNITED KINGDOM · CHINA · MALAYSIA

Nottingham University Hospitals **NHS**  
NHS Trust



**NHS**  
National Institute for  
Health Research

## Down syndrome and glue ear

### How practical and useful is it to conduct further research to evaluate the treatment options for children with Down syndrome and glue ear?

#### Questionnaire for Parents and Carers

This questionnaire is for parents or carers of children with Down syndrome aged between 1 and 11 years of age. Every child and every parent and carer is different and has their own opinions and experiences. This questionnaire is for you to complete to tell us about your experiences and those of your child.

We are also interested in learning more about your views and attitudes on research and at the end of this questionnaire, you will be given the opportunity to take part in further research.

We would be grateful if you could complete the questionnaire as soon as possible. If this is going to be difficult, please contact Dr Lisa Brown on [REDACTED] or email [REDACTED] who will be able to advise.

اگر آپ یہ سوالنامہ پڑھ نہیں سکتے اور اسے کسی اور زبان میں حاصل کرنے کو ترجیح دیں گے، تو برائے کرم لیزا براؤن کو مندرجہ بالا نمبر پر فون کر کے یا شامل کئے گئے لفافے میں ایک خط بھیج کر ہمیں اس سے آگاہ کریں۔

ਜੇਕਰ ਤੁਸੀਂ ਇਹ ਪ੍ਰਸ਼ਨਾਵਲੀ ਨੂੰ ਪੜਨ ਵਿਚ ਨਾਕਾਬਲ ਹੋ ਅਤੇ ਤੁਸੀਂ ਇਸਨੂੰ ਕਿਸੀ ਹੋਰ ਭਾਸ਼ਾ ਵਿਚ ਚਾਹੁੰਦੇ ਹੋ, ਤੇ ਕ੍ਰਿਪਾ ਕਰ ਕੇ ਉਤੇ ਦਿਤੇ ਨੁਮਬਰ ਤੇ ਲੀਸਾ ਬ੍ਰਾਊਨ ਨੂੰ ਟੇਲੀਫੋਨ ਕਰੇ ਜਾ ਫੇਰ ਨਾਲ ਦਿਤੇ ਲਿਫਾਫੇ ਵਿਚ ਪਤਰ ਭੇਜੋ.

*JeŚeli nie są Państwo w stanie zrozumieć treści niniejszego kwestionariusza i chcieliby otrzymać jego kopię w tłumaczeniu na inny język, prosimy skontaktować się telefonicznie z panią Lisą Brown pod ww. numerem telefonu lub wysłać zapytanie w załączonej kopercie zwrotnej*

## Middle ear problems and glue ear

Children with Down syndrome very often have **middle ear problems** involving ear infections (pain, fever, ear discharge) and episodes of fluid in the middle ear known as “**glue ear**” or the medical term **otitis media with effusion (OME)**. It involves a collection of thick or sticky fluid behind the eardrum in the middle ear. This may interfere with a child's hearing but is usually temporary. Treatments might include hearing aids (softband or standard), or an operation to insert small tubes called grommets in the child's ears. Many cases of glue ear get better without treatment, but it is unclear what the best treatment is.

## Health Research

**We are not asking you to take part in an actual study. We are asking for your opinion on taking part, with your child, in health research using observational studies or a randomised controlled trial. This information will help us design future studies.**

**What is observational health research?** In this type of research, a researcher monitors a group (cohort) of patients over a period of time in order to assess outcomes (e.g. hearing loss) and compare the different treatments that participants have received.

For example, a group of children with glue ear could be identified and then followed up over a period of months to see if the children who had grommets had better or worse outcomes than those who used hearing aids.

**What is a randomised controlled trial (RCT)?** In this type of research, the effect of different treatments for a particular condition is studied in two or more groups of patients who are selected at random to receive each treatment. By using random selection, each group is similar in terms of age, gender etc, allowing doctors and researchers to decide with more certainty whether one treatment option is more effective than the other.

For example, one group of children with glue ear could be randomly selected to receive grommets, while the other group could receive hearing aids or it may involve no treatment at all (i.e. watchful waiting) and they are followed up by researchers at standard times. The treatment results are then compared to show which group had the most benefit. Any person who agrees to take part in an RCT can withdraw at any time.

## Section 1 Questions about the health of your child who has Down syndrome

1. Has your child ever had any medical problems with their ears?	<input type="checkbox"/> Sometimes <input type="checkbox"/> A lot of the time <input type="checkbox"/> Not at all <input type="checkbox"/> Don't know
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2. Has a doctor ever diagnosed your child with glue ear?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
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2a. If yes, how often has your child had glue ear since their first birthday?	<input type="checkbox"/> Don't know <input type="checkbox"/> All the time <input type="checkbox"/> At least every month <input type="checkbox"/> 3 or 4 times per year <input type="checkbox"/> Once per year <input type="checkbox"/> Less than once per year
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3. Please briefly describe any other health problems that you are aware your child has.

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## Section 2 Questions about glue ear and how it affects your child

If your child has never had glue ear please go to Section 4, page 5.

1. Do you think glue ear has affected any of the following for your child?

<i>Please tick any you think have been affected</i>		<i>Please describe</i>
<b>Hearing</b> (e.g. turning up the volume on the TV)	<input type="checkbox"/>	..... .....
<b>Listening</b> (e.g. paying attention)	<input type="checkbox"/>	..... .....
<b>Understanding of language and communication</b> (e.g. following instructions)	<input type="checkbox"/>	..... .....
<b>Use of language and communication</b> (e.g. ability to produce speech or use non-verbal behaviour)	<input type="checkbox"/>	..... .....

*(Continued over the page)*

Please turn over

1. (Continued) Do you think glue ear has affected any of the following for your child?

<b>Please tick any you think have been affected</b>	<input type="checkbox"/>	<b>Please describe</b>
<b>Learning</b> (e.g. school progress)	<input type="checkbox"/>	..... .....
<b>Behaviour</b> (e.g. naughtiness or not doing what they are told)	<input type="checkbox"/>	..... .....
<b>Social interaction</b> (e.g. playing with friends, relationships with family members)	<input type="checkbox"/>	..... .....
<b>Any other areas?</b>	<input type="checkbox"/>	..... .....

**Section 3 Questions about the help you and your child have received**

1. Has your child received any help for glue ear?	<input type="checkbox"/> Yes <input type="checkbox"/> No (Please go to Section 4, page 5) <input type="checkbox"/> Don't know
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2. If yes, was this help any of the following and do you think it led to an improvement?

<b>Please tick any help your child has had.</b>	<input type="checkbox"/>	<b>Do you think it led to an improvement?</b>		
		Yes	No	Don't know
Antibiotics	<input type="checkbox"/>			
Surgery: insertion of a ventilation tube (grommet)	<input type="checkbox"/>			
Surgery: removal of the adenoids (adenoidectomy)	<input type="checkbox"/>			
Alternative therapies (e.g. homeopathy, special diet) <i>Please specify</i> .....	<input type="checkbox"/>			
Hearing aid: Conventional behind the ear hearing aid	<input type="checkbox"/>			
Hearing aid: Softband BAHA (Bone Anchored Hearing Aid)	<input type="checkbox"/>			
Radio Aid system at school	<input type="checkbox"/>			
No treatment (i.e. watchful waiting)	<input type="checkbox"/>			
Other type of treatment <i>Please specify</i> .....	<input type="checkbox"/>			

3. What other views do you have on the options for treatment?

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 .....  
 .....

**Section 4 Questions about your views on research**

1. How much do you know about research in general?

- Nothing       A little bit       A fair amount       Quite a lot       A great deal

2. What do you think would be the benefits for your child being involved in health research using observational studies? (See page 2) .....

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3. What do you think would be the problems for your child being involved in health research using observational studies? (See page 2) .....

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4. What do you think would be the benefits for your child being involved in health research using a randomised controlled trial (RCT)? (See page 2) .....

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5. What do you think would be the problems for your child being involved in health research using a randomised controlled trial (RCT)? (See page 2) .....

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6. If your child needed treatment for glue ear in the future, what would encourage you to agree to her/him taking part in health research using observational studies or an RCT?

*Please tick all that apply.*

- Having the time to take part
- Having access to information about what will happen
- Learning about new treatments
- Having any travel expenses met
- My child may be offered a treatment that really helps
- Other (please specify).....

7. If your child needed treatment for glue ear in the future, what would discourage you from agreeing to her/him taking part in health research using observational studies or an RCT?

*Please tick all that apply.*

- Lack of time to take part
- Uncertainty about what will happen
- Cost of travelling to take part
- My child may be offered a treatment that does not really help
- Lack of knowledge about research
- Other (please specify).....

## Section 5 Questions about why people take part in research

1. Here are some reasons why people take part in research. Please indicate how much you agree or disagree with each reason (*tick as appropriate*).

	Strongly Agree	Agree	Disagree	Strongly Disagree
To feel that I am helping people with Down syndrome by participating in research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To feel like I have been given a choice to participate in research by healthcare professionals and that I have been consulted by them.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To feel like a good parent, that I have some control over the effective care of my child's glue ear.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
To have access to increased support from healthcare professionals	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. What other reasons do you think there might be for people taking part in research?

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3. Imagine if you were asked to agree to your child taking part in a randomised controlled trial comparing different treatments (*see page 2*) for glue ear; would you agree?

- Yes  
 No  
 Don't know

4. Imagine if you were asked to agree to your child taking part in an observational study comparing different treatments (*see page 2*) for glue ear; would you agree?

- Yes  
 No  
 Don't know

5. What do you think would make it easier for parents/carers of children with Down syndrome who have glue ear to take part in research?

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## Section 6 Questions about the benefits of taking part in research

1. If future research had to look at one or two good outcomes from a health research study comparing different treatment options for glue ear in children with Down syndrome, which of the following would you put as the most important outcome and which as second in importance? (*please tick as appropriate*).

	Most important outcome	Second most important outcome
For my child's speech, language, and communication with me and others to improve	<input type="checkbox"/>	<input type="checkbox"/>
For my child's hearing to improve	<input type="checkbox"/>	<input type="checkbox"/>
For my child to make progress at school/nursery	<input type="checkbox"/>	<input type="checkbox"/>
For my child's social interaction with others (e.g. with friends and family members) to improve.	<input type="checkbox"/>	<input type="checkbox"/>

2. What else is important for you and your child to gain from research into different treatment options for glue ear in children with Down syndrome?

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 .....

3. What other comments do you have on glue ear and Down syndrome or on this questionnaire?

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 .....  
 .....

## Section 7 Background information

**If you wish to remain anonymous, you may leave this section blank.**

Your Age ..... Your Child's Age ..... Your Child's Gender.. Male/Female (*please circle*)

How many other children do you have (*please circle*)?    0 1 2 3 4 5 more than 5

What are their ages? ..... .....

How would you describe your own educational qualifications:

<input type="checkbox"/> Left school before age 15	<input type="checkbox"/> Further qualification but not university degree
<input type="checkbox"/> Usual school exams for age 15-16	<input type="checkbox"/> University degree
<input type="checkbox"/> Usual school exams for age 17-18	<input type="checkbox"/> Postgraduate qualification

What is your postcode?.....

## Section 8 Further research

We will be inviting a selection of parents and carers to take part in an interview or a discussion group so that they can tell us more about their views on research into treatment options for children with Down syndrome and glue ear and help us design future studies.

- **Interviews** will last about 1 hour and will take place over the next few months in your own home or your local clinic at your convenience.
- **Discussion groups** will last 2 hours and will be held over the summer at times suitable for families at the Research Unit in Nottingham City Centre.
- All your travelling expenses will be paid.

### An invitation to take part

Would you be interested in taking part in an <b>interview</b> so that you can tell us more about your views and experiences?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
Would you be interested in taking part in a <b>discussion group</b> so that you can tell us more about your views and experiences?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know

If you would like to be involved, please include your contact details below, and more information will be sent to you nearer the time.

Name and address: .....

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Telephone: .....

Email: .....

**Thank you for completing this questionnaire.**  
**All answers you have given will be treated in strict confidence.**

**Please return the questionnaire in the enclosed envelope to:**  
NIHR National Biomedical Research Unit in Hearing,  
University of Nottingham,  
Ropewalk House,  
113 The Ropewalk,  
Nottingham NG1 5DU