



The University of
Nottingham

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 Professionals

This questionnaire is for professionals involved in the care and education of children with Down syndrome aged between 1 and 11 years who have glue ear.

This questionnaire is for you to complete to tell us about your understanding and management of glue ear in children with Down syndrome. We understand that children present with different issues and each has different needs and challenges but we would like you to generalise as much as possible in answering the questions. The questionnaire also asks you about your views on future research into treatment options.

All responses will be treated as strictly confidential.

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.

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

This study aims to:

1. Assess the level of current uncertainty regarding the management of glue ear in children with Down syndrome;
2. Assess the feasibility of studying management options by exploring the views of parents/carers and professionals on research involving randomisation;
3. Explore measurable and relevant outcome domains;
4. Undertake a health economic analysis of the value of information to be gained from further research.

Please indicate your discipline/department by ticking the appropriate box

- Audiology
- Speech and Language Therapy
- Ear, Nose and Throat (ENT)
- Teacher of the Deaf
- School Nurse
- Paediatrician
- Audiological Physician
- Other (*please specify*).....
.....

Section 1 Incidence and severity of glue ear in children with Down syndrome

1. Do you have any children with Down syndrome aged between 1 and 11 years on your caseload?	<input type="checkbox"/> Yes If yes, roughly how many? ___ <input type="checkbox"/> No <input type="checkbox"/> Not sure
2. To what extent do you consider yourself to have a specific professional interest in the care of children with Down syndrome?	<input type="checkbox"/> No interest <input type="checkbox"/> A little bit of interest <input type="checkbox"/> A fair amount of interest <input type="checkbox"/> A great deal of interest
3. What proportion of children with Down syndrome in your care, would you estimate, has experienced glue ear?	_____ %
4. Roughly how many children do you see professionally each year with Down syndrome and glue ear?	_____

Section 2 Approaches to clinical management

1. How confident are you that you can explain the benefits and risks of surgical intervention to a parent and their child with Down syndrome who has glue ear?	<input type="checkbox"/> Very confident <input type="checkbox"/> Fairly confident <input type="checkbox"/> A little confident <input type="checkbox"/> Not at all confident
2. How confident are you that you can explain the benefits and risks of non-surgical intervention to a parent and their child with Down syndrome who has glue ear?	<input type="checkbox"/> Very confident <input type="checkbox"/> Fairly confident <input type="checkbox"/> A little confident <input type="checkbox"/> Not at all confident
3. How confident are you that you can explain the benefits and risks of active observation (watchful waiting) to a parent of a child with Down syndrome who has glue ear?	<input type="checkbox"/> Very confident <input type="checkbox"/> Fairly confident <input type="checkbox"/> A little confident <input type="checkbox"/> Not at all confident
4. How much do you understand about the National Institute for Health and Clinical Excellence (NICE) guidelines concerning the care pathway for children with Down syndrome who have glue ear?	<input type="checkbox"/> Nothing <input type="checkbox"/> A little bit <input type="checkbox"/> A fair amount <input type="checkbox"/> A great deal

<p>5. If new guidelines were developed for the care pathway and treatment of glue ear in children with Down syndrome that differed from your current practice, would you <i>please choose one</i></p>	<input type="checkbox"/> Immediately change your practice in line with the guideline? <input type="checkbox"/> Consider the guidelines on the basis of the evidence presented? <input type="checkbox"/> Continue with your current practice regardless of what the guidelines suggested? <input type="checkbox"/> React in a different way? (please specify)
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Section 3 Consequences of glue ear in children with Down syndrome

For a child with Down syndrome, there are many consequences of having glue ear. In the following 3 questions, we would like you to think about:

- Which consequences are the **most frequent** in occurrence?
- Which consequences do you consider the **most significant** for the child/family?
- Which consequences do you personally find the **most challenging** to address?

For each question, please indicate, what you think are, the top three consequences by clicking on the drop down menu to indicate first, second, or third in order of importance. You have the option to add an area if you think there is something we have not included.

1. For a child with Down syndrome who has glue ear, which of the consequences of glue ear are **most frequent**?

Hearing (e.g. turning up the volume on TV)	
Listening (e.g. paying attention)	
Understanding of language and communication (e.g. following instructions)	
Using language and communication (e.g. ability to produce speech or use non-verbal behaviour, gestures)	
Learning (e.g. progress in school)	
Behaviour (e.g. naughtiness or not doing what they are told)	
Social interaction (e.g. playing with friends, relationships with family members)	
Ear infections	
Any other areas (please specify).....	

2. For a child with Down syndrome who has glue ear, which do you consider to be the top three areas in terms of **the significance of the consequence for the child/family?**

Hearing (e.g. turning up the volume on TV)	
Listening (e.g. paying attention)	
Understanding of language and communication (e.g. following instructions)	
Using language and communication (e.g. ability to produce speech or use non-verbal behaviour, gestures)	
Learning (e.g. progress in school)	
Behaviour (e.g. naughtiness or not doing what they are told)	
Social interaction (e.g. playing with friends, relationships with family members)	
Ear infections	
Any other areas (<i>please specify</i>).....	

3. For a child with Down syndrome who has glue ear, which do you consider to be the top 3 **most challenging consequences in terms of your management of the children?**

Hearing (e.g. turning up the volume on TV)	
Listening (e.g. paying attention)	
Understanding of language and communication (e.g. following instructions)	
Using language and communication (e.g. ability to produce speech or use non-verbal behaviour, gestures)	
Learning (e.g. progress in school)	
Behaviour (e.g. naughtiness or not doing what they are told)	
Social interaction (e.g. playing with friends, relationships with family members)	
Ear infections	
Any other areas (<i>please specify</i>).....	

4. If future research had to assess only one or two 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 the child's speech, language, and communication with others to improve.	<input type="checkbox"/>	<input type="checkbox"/>
For the child's hearing to improve.	<input type="checkbox"/>	<input type="checkbox"/>
For the child to make progress at school/nursery	<input type="checkbox"/>	<input type="checkbox"/>
For the child's social interaction with others (e.g. with friends and family members) to improve	<input type="checkbox"/>	<input type="checkbox"/>
For the child's ear infections to improve/disappear	<input type="checkbox"/>	<input type="checkbox"/>
Other outcome <i>please specify</i>	<input type="checkbox"/>	<input type="checkbox"/>
.....		

Please add any comments you might have on the assessment of outcomes

.....

Section 4 Interventions for children with Down syndrome who have glue ear

Children with Down syndrome who have glue ear present many clinical challenges in the choice of intervention. All professionals who work with these children provide intervention in some form whether that be fitting a hearing device, prescribing medication, recommending surgery or providing speech and language therapy.

We are interested to know what influences your decision on intervention in your discipline. We understand that each child presents different challenges but please try to generalise in your answer.

<p>1. Which of these factors influence your decision on intervention?</p> <p><i>(please tick any that apply)</i></p>	<input type="checkbox"/> Age <input type="checkbox"/> Level of hearing <input type="checkbox"/> Family structure <input type="checkbox"/> Parental concern <input type="checkbox"/> Progress at school <input type="checkbox"/> Speech production and understanding <input type="checkbox"/> Any other medical concerns <input type="checkbox"/> Previous response to treatment <input type="checkbox"/> A combination of all the above
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<p>2. Which of these factors most influences your decision on intervention?</p> <p><i>(please tick only one)</i></p>	<input type="checkbox"/> Age <input type="checkbox"/> Level of hearing <input type="checkbox"/> Family structure <input type="checkbox"/> Parental concern <input type="checkbox"/> Progress at school <input type="checkbox"/> Speech production and understanding <input type="checkbox"/> Any other medical concerns <input type="checkbox"/> Previous response to treatment
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3. Here is a list of possible interventions that children with Down syndrome may receive to improve glue ear and/or hearing loss and/or communication difficulties. We would like to know which, in your opinion, are the most effective interventions, in general, for children you have worked with.

Please indicate what you think are the top 3 effective interventions by clicking on the drop down menu to indicate the first most effective, the second most effective and the third most effective intervention. You have the option of adding an intervention if you think there are some we have not included.

Alternative therapies (e.g. homeopathy, special diet) <i>Please specify.....</i>	
Antibiotics	
Decongestants	
Hearing aid: Bone Anchored Hearing Aid (permanent or on a softband)	
Hearing aid: Conventional behind the ear Hearing Aid	
No treatment (i.e. active observation/watchful waiting).	
Speech and language therapy	
Surgery: insertion of a ventilation tube (grommet)	
Surgery: removal of the adenoids (adenoidectomy)	
Surgery: insertion of a ventilation tube (grommet) and removal of the adenoids (adenoidectomy) at the same time	
Other type of intervention <i>Please specify.....</i>	

4. Are there any interventions that you think should **not** be considered as an option for children with Down syndrome who have glue ear? *Please explain*

.....

.....

5. Are there any interventions that you think should **not** be included in a research trial comparing interventions for children with Down syndrome who have glue ear? *Please explain*.....

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.....

6. Is there anything else that you would like to comment on concerning the management of children with Down syndrome who have glue ear, and their families?

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Section 5 Your views on health research

There is very little robust evidence of the benefit of any particular intervention for children with Down syndrome who have glue ear. To address this, the National Institute for Health Research (NIHR) are considering whether to commission some research. This would be a cost and clinical effectiveness study based on randomised control trial or prospective cohort study methodologies. In this section, we would like you to give us your views on future research.

<p>1. In general, what is your view of health research?</p>	<p><input type="checkbox"/> It is essential for developing practice</p> <p><input type="checkbox"/> It can sometimes be useful</p> <p><input type="checkbox"/> Research findings won't change my practice</p> <p><input type="checkbox"/> Health research is a waste of time</p>
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	Observational health study	Randomised controlled trial (RCT)
<p>2. Different methods are used in health research. How confident are you that you can explain an observational health study and a randomised controlled trial (RCT) to a parent of a child with Down syndrome*?</p>	<p><input type="checkbox"/> Very confident</p> <p><input type="checkbox"/> Fairly confident</p> <p><input type="checkbox"/> Not very confident</p> <p><input type="checkbox"/> Not at all confident</p>	<p><input type="checkbox"/> Very confident</p> <p><input type="checkbox"/> Fairly confident</p> <p><input type="checkbox"/> Not very confident</p> <p><input type="checkbox"/> Not at all confident</p>

*If you feel unsure of your understanding of an RCT and an observational health study, please see the information below.

Observational health research: Over a period of time researchers monitor a cohort of patients who have received different interventions and compare outcomes (e.g. hearing loss).

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 or those who had received no intervention.

Health research using a randomised controlled trial (RCT): 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 other groups could receive hearing aids or no treatment at all (i.e. active observation). They would be followed up by researchers at standard times. The outcomes would then be compared to show which group had the most benefit.

3. What do you see as the benefits (if any) of participating in health research for children with Down syndrome who have glue ear?

.....

.....

4. What do you see as the benefits (if any) of participating in health research for you, your practice or the wider community?

.....

.....

5. What do you see as some of the difficulties (if any) of participating in health research for children with Down syndrome who have glue ear?.....

.....

.....

6. Have you ever participated in a randomised controlled trial?	<input type="checkbox"/> Yes as a participant <input type="checkbox"/> Yes as a researcher <input type="checkbox"/> No
If yes, would you do it again?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know
Please explain your answer	
.....	
.....	

7. Imagine you were asked to recruit parents and their children with Down syndrome to take part in a health research study where they received the intervention for glue ear you recommend and were then followed up for 2 years. Would you agree?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> I wouldn't be involved directly in recruitment
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8. Imagine you were asked to recruit parents and their children with Down syndrome to take part in a health research study where they would be randomly assigned to receive different treatments for glue ear. Would you agree?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't know <input type="checkbox"/> I wouldn't be involved directly in recruitment
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Section 6 Facilitators and barriers to RCT recruitment

Research suggests that there may be many factors which encourage clinicians to recruit patients into health research studies. Equally there may be many factors that discourage recruitment but there are few studies that specifically explore the recruitment to trials of children who have Down syndrome.

We are aware that some professional groups such as ENT surgeons are more often responsible for directly recruiting to a trial involving surgical intervention. However, people within other disciplines such as paediatricians, audiologists, speech and language therapists and so on may also influence the decision of a parent or carer as to whether or not their child should participate in a research trial. Although your experience of recruitment may vary, we are interested in the factors that would be important to you in deciding to recruit to a trial or encouraging a parent to agree to their child taking part.

Imagine a scenario where you are asked to collaborate with researchers conducting a randomised controlled trial of interventions for glue ear in children with Down syndrome. You are asked to recruit children to the study and have to explain to parents that their child will be randomly assigned to receive one of 3 intervention options: insertion of grommets; provision of a soft band hearing aid; or active observation (watchful waiting) . Each child would be followed up for 6 months.

1. Looking at the statements below, please indicate the importance of each statement in informing your decision to try to recruit a parent and their child with Down syndrome to take part in a randomised controlled trial or to advise them to do so?

You have the option of adding further statements if you think there are some things we have not included.

Things that might encourage you	Not important at all	Very important	Don't know
Professional factors			
My involvement in the study would cause little or no disruption to my clinical commitments	0 _____	100	<input type="checkbox"/>
I would receive some financial reward for taking part	0 _____	100	<input type="checkbox"/>
Having confidence in my ability to explain the study to parents and to take their consent	0 _____	100	<input type="checkbox"/>
Feeling I have sufficient experience of research	0 _____	100	<input type="checkbox"/>

Child/family factors

The child and his/her family would have the time to take part	0 _____ 100	<input type="checkbox"/>
There would be minimal inconvenience to the child and his/her family	0 _____ 100	<input type="checkbox"/>
All out of pockets expenses for the family would be reimbursed	0 _____ 100	<input type="checkbox"/>

Clinical factors

There is genuine uncertainty within the clinical community about which treatment option is better	0 _____ 100	<input type="checkbox"/>
I personally am uncertain about which treatment option is better	0 _____ 100	<input type="checkbox"/>
I would be contributing to determining the most effective treatment	0 _____ 100	<input type="checkbox"/>

Personal factors

I would be helping individuals with Down syndrome by encouraging them to participate in research	0 _____ 100	<input type="checkbox"/>
I would increase my awareness and experience of research	0 _____ 100	<input type="checkbox"/>
Taking part would improve my CV	0 _____ 100	<input type="checkbox"/>

Other factors (please add as many as you think are relevant)

.....	0 _____ 100	<input type="checkbox"/>
.....	0 _____ 100	<input type="checkbox"/>

Not important at all	Very important	Don't know
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Things that might **discourage** you

Professional factors

Not having confidence in my ability to explain the study to parents and to take their consent	0 _____ 100	<input type="checkbox"/>
Not having research experience	0 _____ 100	<input type="checkbox"/>
I would lose my professional autonomy to decide what is the best treatment	0 _____ 100	<input type="checkbox"/>

Child/family factors

Additional non-routine procedures would be involved for the child	0 _____ 100	<input type="checkbox"/>
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Clinical factors

The research might have a detrimental effect on my relationship with the family	0 _____ 100	<input type="checkbox"/>
There may be a risk of harm or side effects from the treatment options	0 _____ 100	<input type="checkbox"/>
The research might take priority over the needs of the patient	0 _____ 100	<input type="checkbox"/>

Other factors (please add as many as you think are relevant)

0 _____ 100	<input type="checkbox"/>
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What else is important for you to gain from research into treatment options for glue ear in children with Down syndrome? *Please write a comment.*

Section 7 Your invitation to take part in further research

We will be inviting some respondents to take part in a further stage of the research involving the Delphi technique. This is a method of reaching an agreement amongst a selected group of varied professionals by asking questions during a small number of rounds and identifying themes in the answers given. The questions will concern views on treatment options and reliable outcome measures and also on future research.

Who, Where and When? The Delphi review will be conducted by email on three occasions in 2012 with professionals who have been selected on the basis of their responses to this questionnaire. On each occasion, we would ask you to complete an on-line questionnaire that would take 15-20 minutes to complete.

Further information about this research can be found here <<link>> or by e-mailing your questions to [REDACTED]

An invitation to take part

If you would be interested in taking part in a Delphi review so that you can tell us more about your views and experiences, please include your contact details below, and we will contact you again in the next few weeks.

Name Email:.....

**Thank you for completing this questionnaire.
All answers you have given will be treated as strictly confidential.**

If posting, please return to:
NIHR National Biomedical Research Unit in Hearing,
University of Nottingham,
Ropewalk House,
113 The Ropewalk,
Nottingham NG1 5DU4.73