



Participant Information Sheet/Consent Form for Clinical Experts

Perth Children's Hospital

Title

*Evidence-based clinical guidelines
for prevention and management of respiratory
disease in young people with cerebral palsy.*

Short Title

*A Delphi Study to determine clinical guidelines for
prevention and management of respiratory disease in
young people with cerebral palsy*

Protocol Number

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**Research Team
Investigator(s)**



Part 1 What does my participation involve?

1 Introduction

We would like to invite you to take part in a Delphi consensus study. Before you decide whether or not you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

What is a Delphi study?

The Delphi technique seeks to obtain consensus on the opinions of experts, termed panel members, through a series of structured questionnaires. As part of the process, the responses from each round are fed back in summarised form to the participants who are then given an opportunity to respond again to the emerging data. The Delphi is therefore an iterative multi-stage process designed to combine opinion into a group consensus.

If you decide you want to take part in the research project, you will be asked to consent by clicking on the link to proceed to the study survey. By clicking the link to the study survey you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the researchers using the information you provide as part of this research

You should save this Participant Information so that you retain our contact information.

2 What is the purpose of this research?

Respiratory disease is the leading cause of hospital admissions and deaths in children with cerebral palsy (CP). Despite vast improvements in medical care and technology over the past 40 years, survival of children with CP is much the same as it was in the 1970s. Recent research has uncovered risk factors for identifying these young people earlier. However, there is currently no consensus about the most effective ways to prevent or manage respiratory illness in young people with CP.

The overarching aim of this project is to develop evidence-based clinical practice guidelines for the prevention and management of serious respiratory disease in children and young people with CP. We are currently conducting a systematic review of the literature however as the literature is inadequate we are using the Delphi method to reach expert consensus on prevention and management guidelines. This development of the guideline is a necessary prerequisite to our longer term goal of designing an appropriate intervention study.

As an established expert in this field we are keen to gain your views in developing the consensus statement for the prevention and management of respiratory illness in young people with CP. We plan to recruit up to 60 Delphi participants consisting of

physicians, physiotherapists, speech therapists and selected experts in respiratory management of people with CP. The developed guidelines will then be discussed at separate, later, round-table consensus meeting to derive the final expert clinical decisions. Delegates at this round table meeting will comprise the CP Respiratory Research Team identified at the top of this information sheet. The final clinical guideline preparation will follow the Appraisal for Guidelines for Research and Evaluation II (AGREE II) guidelines.

3 What does participation in this research involve?

We are inviting you to participate as a Delphi expert panel member. This would involve completing a brief questionnaire using an online survey. It is envisaged that this should take approximately 30 minutes. The first round of survey will contain open-ended questions constructed by the investigators based on theoretical principles and rationale for interventions and approaches for the management of respiratory illness in children with CP.

You would subsequently receive a reminder of your responses, a summary of the group's responses and a further online questionnaire to rank each item of a generated list of guideline statements on agreement. You will be asked to rank the items using 7-point Likert scale (1 - strongly disagree; 2 - moderately disagree; 3 - slightly disagree; 4 - not sure or no comment; 5 - slightly agree; 6 - moderately agree; 7 - strongly agree. This process would continue until a group consensus is achieved or three Delphi rounds have been completed.

In order to allow timely conclusion of the study we would respectfully request a response time of 2 weeks for completion of each round.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study investigators or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

4 What do I have to do?

You will be asked to check a box confirming that you are a health professional that meets our inclusion criteria for an expert in this area. To be considered an expert you must have a suitable professional qualifications required for diagnosing and/or managing respiratory illness/dysphagia in children in the fields of clinical medicine, physiotherapy, occupational therapy, speech therapy, and nursing **and** have been working in the field of CP with at least 10 years clinical experience; or, be a researcher or academic expert who has authored at least three publications (reviews, intervention

articles, or textbooks) relating to respiratory management of people with neurological problems.

5 Other relevant information about the research project

As part of the Delphi, consumer input will also be obtained from people living with CP and/or their carers to inform acceptability and utility of identified prevention and management options.

At the completion of the Delphi study, a Consensus Statement of assessment and management of respiratory illness in children with CP will be prepared and distributed to the Delphi panel and this will be used together with evidence from the systematic review to inform the clinical guidelines. A multidisciplinary local panel that includes the principle researchers, clinicians from all relevant disciplines, a health economist, and two consumers (one adult with CP and one parent of a child with CP) will define the purpose of the guidelines, the boundaries of the clinical problem, the settings in which the guidelines could be applied, the interventions to be covered by the guidelines, and the audience(s) for the guidelines (including how many versions of the guidelines will be required). The panel will also be asked to define the outcomes (e.g., hospital admissions, deaths, quality of life measures).

Clinical practice guidelines will be prepared in adherence to the National Health and Medical Research Council's recommendations, and will be submitted to the Council for endorsement. Appraisal of Guidelines for Research and Evaluation (AGREE) II criteria will also be used to assess the guidelines.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage and this will not influence any relationship or role you have with the institutions involved in this research.

7 What are the possible benefits of taking part?

Your responses will inform future research and practice. We anticipate gaining valuable expert knowledge about interventions around prevention and management of respiratory illness, evidence translation and about how health professionals use evidence.

8 What are the possible risks and disadvantages of taking part?

There are no questions within this survey expected to cause emotional distress, embarrassment or discomfort.

9 What if I withdraw from this research project?

You are free to withdraw from this study at any time without prejudice.

10 What happens when the research project ends?

The collected responses will be stored in accordance with Australian Privacy Regulations, and kept as a data file on a secure online server for 10 years. After this, the file will be deleted. Should any subsequent publication support publication of anonymised data, this will be published as part of the publication. A report of this study will be submitted for publication, but no individuals will be identifiable in this report.

At the end of the project, all participants will be emailed a summary of the findings and be invited to knowledge transfer workshops in the capital city closest to them. It is expected that the results will be published in a peer reviewed journal and the results presented at relevant conferences by the research team.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

The responses to this survey are confidential. Your email will be linked with your answers but only the research team will view your responses. The survey is online through a survey platform called REDCap. REDCap is a data capture and storage system, made specifically for academic research. We will be utilising REDCap™ through the Telethon Kids Institute who administer the system and make it available for researchers from Perth Children's Hospital. The system is maintained and administered by a small team of experienced database specialists, all of whom have signed confidentiality agreements, with Telethon Kids Institute. The system runs on secure, password-protected, encrypted servers located on premise at Telethon Kids Institute, Perth, Western Australia with offsite backup. Access, both virtually and physically, to the servers is restricted to IT specialists. All access is logged and audited to ensure only those people with authority access the data.

Any information obtained in connection with this research project that can identify you will remain confidential and only accessible by the Principle Investigators in this research team. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

The collected online survey responses will be stored in accordance with Australian Privacy Regulations, and kept as a data file on a secure online server for 10 years. After this, the file will be deleted. Should any subsequent publication support publication of anonymised data, this will be published as part of the publication.

At the end of the project, all participants will be emailed a summary of the findings and be invited to knowledge transfer workshops in the capital city closest to them. It is

expected that the results will be published in a peer reviewed journal and the results presented at relevant conferences by the research team.

No individuals will be identifiable in this report or at any of the presentations.

12 Who is organising and funding the research?

This research project is being coordinated by *Dr Noula Gibson on behalf of the broader research* between Ability Centre, Perth Children's Hospital, Royal Children's Hospital, Melbourne and the Murdoch Children's Research Institute, Melbourne, Lady Cilento Children's Hospital, Brisbane, The Children's Hospital at Westmead and the Sydney Children's Hospital. Funding for this project has been received from the Cerebral Palsy Alliance Research Foundation and the American Academy of Cerebral Palsy and Developmental Medicine.

You will not benefit financially from your involvement in this research project

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

13 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of *Child and Adolescent Health Service, Perth Western Australia (CAHS HREC)*.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

14 Further information and who to contact

If you would like any more information about this project you can contact Dr Noula Gibson, Chief Principle Investigator on +61 411588917, or at research@abilitycentre.com.au

If have any concerns and/or complaints about the project, the way it is being conducted or your rights as a research participant, and would like to speak to someone independent of the project, please contact the Executive Director Medical Services at CAHS *via* the Perth Children's Hospital switchboard on 6456 2222. Your concerns will be drawn to the attention of the Ethics Committee who is monitoring the study.

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project.

Please note that by proceeding to the survey you are agreeing to participate in this study.