

(REC reference number: 18/NW/0022)

**Identifying the Main Outcomes for Cauda Equina Syndrome: The Delphi Survey and Consensus Meeting**

TO PARTICIPATE IN THE DELPHI SURVEY, PLEASE GO TO **http://bit.ly/cesdelphi**

**What is this about?**

We are trying to decide which outcomes are the most important for patients with Cauda Equina Syndrome (CES). This would involve filling out an online questionnaire and attending an optional meeting.

**What is an outcome?**

An outcome is the result of a medical condition that directly affects the length or quality of a patient’s life.The effect of a significant medical condition upon a patient can lead to many different outcomes, all of which can be assessed.  The outcomes experienced can be different from one person to the next and may not be experienced by everybody.

Doctors and researchers must assess these issues in a research study.

For example, in a study looking at patients with Cauda Equina Syndrome (CES) researchers may analyse outcomes such as:

-bladder function

-bowel function

-back pain

But there may be many more outcomes that matter to patients and healthcare professionals…

**What are the challenges in measuring outcomes?**

By comparing the outcomes ofCES patients we can study what time from symptoms to operation, surgical procedure and other treatments may be best required. This is by combining the information on outcomes from a number of different research studies.

If the same outcomes are measured in all research studies, this is easy to do. But if different outcomes are measured in different research studies this causes problems as we are not comparing like with like. Unfortunately, this is common.

**What is the solution?**

We want all research studies in Cauda Equina Syndrome to use the same **main** group of outcomes. This would make it a lot easier to study treatment of this disabling condition. When a set of main outcomes has been agreed for a health condition, it is called a ‘**core outcome set**’. If all studies measured and reported all the main outcomes, we could

* Bring together all the studies to get a better understanding of the best management for CES.
* Avoid the problem of some studies only reporting a selection of the outcomes that have been measured. For example, ‘cherry-picking’ the best outcomes to report and withholding the bad results

**What is the purpose of the CES study?**

To develop **the main outcomes** important to CES patients for future research studies to use.

**How are the most important outcomes agreed upon?**

Deciding which outcomes should be the main outcomes requires help from different groups of people.

These outcomes have to be relevant to health professionals, but more importantly, they have to be relevant to patients. Researchers also need to make sure that all these experts – patients and healthcare professionals – agree on the main outcomes, also called the “core outcome set.”

The **‘core outcome set’** will be decided upon in the CES study using a **Delphi Survey and consensus meeting**. This is a type of anonymous survey with patients and healthcare professionals.

**What happens if I take part?**

Delphi Survey

Taking part involves completing a survey on two occasions. Your email address, demographic details, date of surgery and your residing location will be requested. Completing the survey can take up to 30 mins on each occasion. You will see a list of different outcomes and be asked to rate how important it is for researchers to measure each of these in their studies.

The outcomes were identified by looking at completed research studies to see what they measured, and from interviews with CES patientsto see what they thought should be measured. You can add any additional outcomes that you think are missing from the list, which will be considered for inclusion by the research team. Once you have completed the survey the results will be analysed by the CES study team. **No one else will see your ratings.**

Once the results have been analysed you will be invited to take part in a **second survey**. This will show how you rated the different outcomes compared with the ratings of others who took part.

It is expected that people will naturally differ in how they rate different outcomes; there are no right or wrong answers! Using this information, we will ask you to reflect on your own view and on the view of the other people who took part. We will then ask you to re-score each item, either sticking with your original score or changing it.

It is **very important** that you complete both surveys – your opinion really matters and cannot be counted if you only complete the first survey. Having said that, you are free to pull out at any time and this will have absolutely no impact on your clinical care.

Consensus meeting

This is optional. You are invited to take part in a consensus meeting when registering for the Delphi. If you have completed all the rounds of the Delphi you will be sent the details of the consensus meeting if you wish to attend and your contact details will be requested. If there is an overwhelming response from participants then not everyone will be invited to the meeting and we will select participants to obtain a varied sample. If you attend it will be a full day event, which takes place in Liverpool, UK attended by participants (patients and healthcare professionals) where the outcomes from the Delphi will be finally decided for inclusion into the core outcome set by online voting. There is also the chance to discuss your views with other key stakeholders and a facilitator.

Advantages/ Disadvantages of participation

The advantage is that you will be able to contribute to this novel research about CES through completing the Delphi Survey and attending the consensus meeting. Apart from the time taken to complete the Delphi Survey and possibly attending the consensus meeting there are no other disadvantages seen to participating.

**What are the total numbers expected to take part in this study?**

We are taking a “pragmatic” approach to this study. This means the more participants we have involved for the Delphi process the better the agreement will be. We would estimate 250 participants in the Delphi and 30 to 40 participants to attend the consensus meeting.

**Are there any risks in taking part?**

For the Delphi, all participant responses are anonymous to other participants. You are not asked about your personal experience but you are asked which outcomes you feel are important in this condition. Some outcomes may be sensitive in nature. If you feel you are too stressed or upset to continue you can stop the assessment at any time and withdraw from the study. You will not need to provide a reason for doing this and it will not influence your ongoing medical care.

If you are concerned about the feelings you are left with after completing the questionnaire please discuss this with CES support groups (details provided below). The research team would also be grateful to hear of this so that we can monitor any difficulties participants have and make any changes which are warranted to the study.

During or after the consensus meeting, if you have any concerns you can speak to the clinicians (Tony Marson, Martin Wilby and Simon Clark) who are part of the research study team and who can advise you appropriately. For example, if a question regarding a body function makes you reflect on your own negative personal experience and you wish to talk about it or you have concerns about how the day is running.

How to make a complaint

If you are unhappy, or if there is a problem, please let us know by contacting research team (details below) and we will try to help. If you feel you cannot come to us with then you should contact our university’s Research Governance Officer (Tel: 0151 794 8290; [ethics@liverpool.ac.uk)](mailto:ethics@liverpool.ac.uk)).

**Who is conducting the research?**

**Nisaharan Srikandarajah** is a clinical research fellow at The University of Liverpool and a neurosurgical trainee.

He is conducting the CES study with **Martin Wilby**, Consultant Neurosurgeon; **Simon Clark**, Consultant Neurosurgeon; **Tony Marson**, Professor of Neurology; **Paula Williamson**, Professor of Biostatistics; **Adam Noble**, Psychological Sciences lecturer at The University of Liverpool.

**Confidentiality and data protection**

When you register, your personal information will be stored securely and not shared with anyone outside the CES study team. Only the study team will have access to your ratings. All data collected for this study will be kept safely and securely on computer. Any identifiable information will be destroyed at the end of the study.

Your ratings will be stored at the University of Liverpool for up to 10 years in case queries arise and it is necessary to check that the study has been carried out properly. This data may also be used for future research. If you do not wish the record of your ratings to be stored they will be destroyed at the end of the study. Please email Nish Srikandarajah if this is the case. Professor Tony Marson is the primary supervisor for this study and will be responsible for all study data.

**Contact for further details:**

**Email:** [nishsri@liv.ac.uk](mailto:nishsri@liv.ac.uk) **OR**

**Number**: 01515295463 **OR**

**Address**: Nisaharan Srikandarajah, Room 2:29, Clinical Sciences Centre, University of Liverpool, Lower Lane, Liverpool, L9 7LJ

If you are upset or concerned following completion of the questionnaire please contact these organisations for further support:

CESA (Cauda Equina Syndrome Association)

Web address: http://www.ihavecaudaequina.com

Email: support@ihavecaudaequina.com

Telephone: 0333 577 7113

Cauda Equina UK

Web address: https://caudaequinauk.org.uk

Email:  info@caudaequinauk.org.uk

Telephone: [0845 602 1993](https://www.google.co.uk/search?client=safari&rls=en&dcr=0&ei=lfpuWrGKD87ewQLJpaqYAg&q=caudae+quina+leicester+charoty&oq=caudae+quina+leicester+charoty&gs_l=psy-ab.3...7175.8822.0.9029.8.8.0.0.0.0.212.1007.4j2j2.8.0....0...1.1.64.psy-ab..0.7.907...33i160k1j33i21k1.0.Bhnkj9zksnc)

Cauda Equina Foundation

Web address: https://www.caudaequinafoundation.org

Spinal Injuries Association

Web address: https://www.spinal.co.uk

Email: sia@spinal.co.uk

Telephone: 0800 980 0501