AOSpine RECODE-DCM Study

Participant Information Sheet: DELPHI Surveys

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Introduction

You are being asked to take part in a research study. Please read this explanation about the study, including its risks, benefits and GDPR statement, before you decide if you would like to take part. You should take as much time as you need to make your decision. If there is anything you do not understand, you can contact the study investigators by email at admin@recode-dcm.com. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

What is Degenerative cervical Myelopathy?

Degenerative cervical myelopathy (abbreviated to DCM) is a condition where 'wear and tear' arthritis ('degenerative') affects the part of the spine in your neck ('cervical'), causing structural changes that compress and damage your spinal cord ('myelopathy'). DCM is also known as "cervical spondylotic myelopathy" or "cervical stenosis".

It is a common disease, estimated to affect up to 5% of people over the age of 40. Unfortunately, it is also disabling, with very few patients making a full recovery and therefore being left with problems such as pain, difficult using their hands or difficulty walking. More information about the disease can be found at **www.myelopathy.org.**

Why is this study being carried out?

In order to change the lives of those affected, we need to improve our understanding of the condition. This requires research. Currently, researchers are working on this problem all over the world, but collectively this process is not as efficient as it could be: for example, research is performed that is not needed (i.e. it seeks to answer a question that has already been answered) or conducted in such a way that the findings cannot be understood (i.e. key measurements were not recorded). This is wasteful and could be improved by developing recommendations for researchers to follow in the future

RECODE-DCM (**RE**search objectives and **CO**mmon **D**ata **E**lements for **D**egenerative **C**ervical **M**yelopathy) aims to shape the way future DCM research is carried out, by developing a number of recommendations to improve research efficiency.

Our aims are to:

1. Establish a standardized definition for DCM.

2. Create list of unanswered DCM research questions, ranked according to priority.

3. Create a standardized set of baseline characteristics and outcomes we should be measuring in DCM research. An *outcome* is a consequence of a medical condition that directly affects the length or quality of a patient's life (e.g. pain). A *baseline characteristic* is something about an individual and/or their DCM journey which effects the interpretation of *outcomes* (e.g. age, DCM severity).

In essence, RECODE-DCM hopes to inform the focus of future DCM research and encourage the consistent recording of critical information. This process is being led by the AO Spine foundation, primarily through researchers at the University of Cambridge, but involves people from around the world.

How are recommendations developed?

In order to produce recommendations that are right and meaningful, it is important to listen to all the different 'experts' involved; those living with the condition, and those working to understand or treat it. We call this a consensus process and it starts by gathering lots of general information, and using feedback from everyone involved, boil this down to what is considered essential. Please see our study video which gives an overview of the process: https://recode-dcm.com/more-information

You have been approached as an expert we should listen to, and we would be grateful for your opinions.

What does participation involve?

The first stage of this consensus process will use a series of online surveys, which is called a 'Delphi'. A Delphi is a technique where a group of experts are asked a series of questions asking them rate which outcomes, characteristics, etc. they think are most important. This information is then summarized and fed back to the group, before they are asked to answer the questions again. This is a very effective way of reaching lots of experts and bring their opinions together to produce a shortlist of recommendations that the majority of our experts have agreed are important.

In order to minimize the amount of time required of you, the project has been broken down into subsections. Therefore, once you have registered you will be randomly allocated to work on a few of the overall project aims.

The face-to-face meeting will follow the online surveys and address any items the group seem undecided upon.

How do I get involved?

If you would like to participate in this process, you will need to complete an online registration form. This asks you a series of basic questions to understand what type of expert you are. After registration, you will be allocated to one of the Delphi surveys. Completing a survey can take up to 30 mins each and the process is entirely anonymous. You will be randomly allocated to answer some but not all of the aims; this has been done to reduce the time required of you. Having completed the first survey, the findings will be summarized and fed back to you. All feedback will be anonymous. You will then have the opportunity to answer the survey again. Generally, this can be done using two rounds of surveys, but sometimes more are required if opinions are very

different.

It is very important that you complete all rounds of the survey, as without full completion, we are unable to add your valuable opinion to our study. It may also mean some key groups are underrepresented and influence the final findings. However, please be aware that you are free to withdraw from the study at any point.

What happens afterwards?

Face-to-Face Consensus Meeting

A number of participants will then be invited to join our team at a consensus meeting to help finalize the study results. This meeting will be at an international spine conference. We aim to have fair representation of patients, carers, healthcare professionals and researchers. At the meeting, study results will be refined by a final round of discussion and voting which will focus on views that did not reach consensus levels of agreement during the survey stage.

Are there any benefits related to participating in this study?

You will have the opportunity to be listed as a collaborator for this large international study, including on all published material. You will have been part of research that hopes to meaningfully improve the lives for people with DCM.

Are there any risks related to participating in this study?

Some personal information must be collected in order to carry out this study. This includes your name, age, gender, email, organisation, country of residence and profession.

All data, including identifiable information, will be securely stored and stringently monitored on our online database. It will not be used for any purposes outside of this study, and therefore not shared with anyone outside of the research team in this organisation and external research organisations, such as universities and commercial companies, in this country and abroad for scientific research purposes. If data needs to be shared for the purpose of this study, it will be done so anonymised. Data collected will be destroyed after 10 years. This ensures any queries in the future about our study procedure could be answered in the future if required. If you do not wish the record of your ratings to be stored, please contact us and they will be destroyed at the end of the study. If you choose to withdraw from the study, your confidential information will be destroyed immediately, but your anonymised opinions given thus far retained.

Study results will be disseminated through academic research publications and will be shared with the participants.

There are no other risks involved with participating in this study.

GDPR statement

In addition to the above, our study will abide by the GDPR statement set out by the University of Cambridge. Please find further details and contact information for this University-wide statement at the following link: https://www.information-compliance.admin.cam.ac.uk/data-protection/research-participant-data

Conflict of Interests

In order to ensure this process is open and transparent, it is important that all participants share any information that could influence their choices or opinions. This is called a Conflict of Interest

declaration and will be sought at registration (please see separate Conflict of Interest Information Form – available at: https://recode-dcm.com/more-information). It is not used to include or exclude your opinion, but to ensure transparency.

Voluntary Participation
Your participation in this study is voluntary. If you agree to participate in this study, you have the right to withdraw at any time you choose. If you wish to do so, please contact the study team.

Questions about the Study
If you have any questions, please contact admin@recode-dcm.com
Also, please see our study webpage at: www.recode-dcm.com
If at any point you need any additional support, please contact our charity partner: www.myelopathy.org

BY COMPLETING THE REGISTRATION FORM AND ENTERING THIS SURVEY, IT IS TAKEN THAT YOU HAVE AGREED TO PARTICIPATE IN THIS RESEARCH STUDY