



STUDY TITLE: SCOL-QoL: a new patient reported outcome measure for assessing long-term psychosocial outcomes of adolescent idiopathic scoliosis following no intervention, bracing only, or any spinal fusion surgery

We would like to invite you to take part in this original study being carried out by a team of researchers led by Dr Lesley Dibley, Centre for Chronic Illness and Ageing, Institute for Lifecourse Development at The University of Greenwich, London. Lesley is a chronic illness researcher and the mother of a daughter who had long fusion for adolescent idiopathic scoliosis (AIS) a decade ago. The research team includes an exercise and rehabilitation researcher, a medical sociologist, an expert in medical ethics, a specialist physiotherapist working with people having spinal fusion surgery, and four people with AIS who have or have not had surgery. This study aims to develop a new questionnaire informed by the experiences of those living with AIS, so that they can report outcomes relevant to the issues that matter to them.

You should only take part if you want to; choosing not to take part will not disadvantage you in any way. Before you decide if you want to take part, it is important that you understand why the research is being carried out and what you would be asked to do. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. You can contact us using the details on the final page.

What is this study about? We are designing a new Patient-Reported Outcome Measure (PROM) to provide clinicians with a new quality of life psychosocial outcomes tool to assess long-term outcomes in people who have been diagnosed with Adolescent Idiopathic Scoliosis (AIS), and may or may not have had bracing or surgical intervention to correct this. We have done the first phase of the study and have collected data from people about their experiences of life with fused or unfused AIS. WE now need to deliver a DELPHI study to determine consensus on the most important items to include in the new PROM.

Why do you need my help? You are being asked to participate as you are either a spinal surgeon or specialist physiotherapist working with people with AIS. Your expertise and contribution will ensure we produce a new PROM which meets patients' and clinicians' needs. We would like to ask for your help with our online Delphi study.

What will happen if I do decide to take part? We will check some demographic details with you (profession / specialism, job title, years working with people with AIS, experience with modern spinal fusion methods) to confirm your eligibility for the study. We will use this information when we publish the study to anonymously describe participants, thus verifying that we had the right people taking part.

For the Delphi study, you will be asked to rank items for the draft PROM in order of importance. This may take four or five rounds, continuing until consensus is reached. Each round of ranking will take about 20 minutes of your time, and we expect four or five rounds. We are also inviting people with

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AIS and their significant others to participate in this DELPHI survey, so that we produce a PROM which contains items that are important to patients, their significant others, and clinicians.

Before you take part, we will remind you about the study and give you the chance to ask questions, so that you may give informed consent. You will be asked to sign a consent form confirming your involvement in the study, which we will countersign and send back to you as a PDF that cannot be altered.

How will the research be done? The DELPHI study will take place online. You will be sent an electronic link to access the online forms via a programme called Qualtrics, and given a unique Study ID number to use. You will not be able to be identified.

Who can take part? We are looking for male and female spinal surgeons and specialist physiotherapists from all four member countries of the UK, with a range of ages, who:

- have current registration with the professional regulatory body relevant to their specialism
- are currently practicing as a specialist spinal surgeon with experience of modern (rod and pedicle screws) fusion surgery methods OR
- are currently practicing as a specialist physiotherapist with experience of caring for patients who have had modern spinal fusion surgery, AND
- have at least three years' experience in the specialist role

You will need to have access to a private computer with internet connection, to avoid any difficulties with NHS firewalls. Even if you offer to take part, you may not be invited to do so if more people offer to take part in the study than are needed. We will let you know one way or the other.

Are there any risks to me in taking part? The study is very low risk for clinicians and no adverse consequences are anticipated.

What about confidentiality and anonymity? Your personal details (name, contact details) will remain confidential to Dr Lesley Dibley and Drs Essex, Hanrahan and Markowski (the research fellows on the study) and will not be shared with anyone else. We will only use these details to contact you about this study. Personal data will be stored in line with the General Data Protection Regulations (GDPR) and deleted as soon as the study is completed. Other demographic data we collect from you will be reported anonymously. You will not be able to be identified.

If you agree to take part in the online Delphi survey, your identity will not be linked to your data – participation will be anonymous. In any reports or publications, anything which identifies you will be removed. We will use a study number or pseudonym to represent you instead.

What are the possible benefits? Your contribution will help us to develop the new PROM and demonstrate that it is 'fit for purpose'. We will be able to address several of the top priorities for research identified by the BSRF, and continue our research endeavours to provide information which informs government policy (such as that related to definitions of disability), employment rights (including enabling practices to facilitate employment in people facing challenges) and health care (including understanding that the consequences of AIS may not end when clinical treatment is

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concluded). We will send you a summary of the findings of this part of the study, unless you tell us you do not want to receive this.

What will you do with the results of the study? The new PROM will enable people who are diagnosed with AIS to accurately report the impact of their diagnosis and treatment on all areas of their life. We will also publish at least two academic papers arising from the whole study, present our findings at a range of medical and nursing conferences, and provide a report to the BSRF. All data used in academic papers, conference presentations and reports will be anonymous. You will not be able to be identified. We also anticipate a follow-on study to use the new SCOL-QOL in a future longitudinal cohort study.

Who is funding the study? This study is not receiving external funding but is being hosted by the University of Greenwich.

Do I have to take part? It is up to you to decide whether to take part in this study or not. Even if you decide to take part, you are still free to withdraw from the study at any time up to 30th June 2024 without consequence. After then, the data you provide will have been analysed and combined with all other data. You do not have to give a reason for withdrawing.

What happens now? You should spend at least 24 hours deciding if you want to take part or not. If you *do not* wish to take part, you do not have to do anything else. If you *do* want to take part, please contact us using the details below:

Dr Lesley Dibley Reader in Nursing Research and Education

University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing

Email: L.B.Dibley@Greenwich.ac.uk

I am currently working from home: please contact me by email

Dr Ryan Essex, Research Fellow

University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing

Email: R.W.Essex@Greenwich.ac.uk |

I am currently working from home: please contact me by email, or via the study mobile number provided

What if I need to know more, before I can decide? For information and independent guidance about taking part in medical research, please visit: <http://www.nihr.ac.uk/get-involved/take-part-in-research.htm>

What if there is a problem? If you have a concern about any aspect of this study, or need more information, please contact Dr Lesley Dibley using the details above. Lesley will do her best to answer your questions. If you have a complaint, you should talk to a member of the research team who will try to answer your questions.