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Alamrani, Samia; Gardner, Adrian; Falla, Deborah; Russell, Emily; Rushton, Alison B; Heneghan, Nicola R

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Content validity of Scoliosis Research Society questionnaire-22 revised (SRS-22r) for adolescents with idiopathic scoliosis: protocol for a qualitative study exploring patient's and practitioner's perspectives

Samia Alamrani ,[1,2] Adrian Gardner,[3] Deborah Falla ,[4] Emily Russell,[5] Alison B Rushton ,[6] Nicola R Heneghan [4]

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For numbered affiliations see end of article.

Correspondence to
Samia Alamrani;
SXA1258@student.bham.ac.uk

ABSTRACT

Introduction Content validity is the most important measurement property for any patient-reported outcome measure (PROM). It being the extent that the PROM measures important concepts that are relevant to the population of interest. Adolescent with idiopathic scoliosis (AIS) is the most common spinal deformity in paediatric populations, with the Scoliosis Research Society questionnaire-22 revised (SRS-22r) a commonly used PROMof quality of life. In the absence of existing evidence, a content validity study for SRS-22r is needed to confirm its suitability for AIS. Thus, this study aims to investigate the content validity of SRS-22r for AIS. A secondary aim is to explore healthcare professional (HCP) perspectives of the barriers and facilitators to using outcome measures in AIS.

Methods and analysis Qualitative study reported according to COnsolidated criteria for Reporting Qualitative Studies. A purposive sample of AIS (n=10–15, Cobb angle >25°, aged 10–18 years) will be recruited for online semi-structured interviews. A convenience sample (n=10–12) of HCP with clinical and/or research experience in AIS will be recruited for a focus group discussion. Topic guides and age-relevant documents are informed by existing evidence and developed using a framework of concept elicitation and cognitive debriefing. Audio-recordings will be transcribed verbatim, coded, analysed and synthesised using interpretive phenomenology analysis. Themes that generated from the analysis will be used as codes that will then be mapped to the SRS-22r contents.

Ethics and dissemination The Health Research Authority and Health and Care Research Wales approval have been granted (IRAS 289888). Study findings will be disseminated through publications in peer-reviewed journals and conference presentations.

Strengths and limitations of this study

- This will be the first study to explore the content validity of the Scoliosis Research Society questionnaire-22 revised and its suitability for adolescent with idiopathic scoliosis (AIS).
- Purposive sampling technique will be used to ensure diversity of the sample.
- Interpretive phenomenology analysis will be used to understand experiences of AIS to their health condition and its associated treatment.
- The small sample size and recruitment from one site may limit the transferability of study findings.

INTRODUCTION

Adolescent with idiopathic scoliosis (AIS) is a scoliosis of unknown cause between the ages of 10–18 years.[1] It is the most common spinal deformity among paediatric patients,[2] with prevalence ranging from 1% to 3%.[3] The AIS may experience health problems including back pain,[4] psychological stress and respiratory dysfunction[5] which can significantly impact quality of life (QoL).[6]

Patient-reported outcome measures (PROM) are commonly used to evaluate QoL and provide patients' perceptions about their health condition and its associated management.[7] A PROM should exhibit good content validity to be recommended for use,[8] this being 'the degree to which elements of an assessment instrument are relevant to, and representative of, the targeted construct for a particular assessment purpose'[9 (p238)]. It is an imperative to the other forms of validity as it shows that all aspects of interest have been sufficiently captured in the PROM and that it is suitable for the intended use.[8 10]

The Scoliosis Research Society-22 revised (SRS-22r) questionnaire is the frequently used PROM for AIS.[11] It has been selected as the preferred PROM in the Core Outcome

Study for young individuals with spine deformity for evaluating the core outcome domains such as self-image, physical functioning, pain and participation.[12] The first version of the SRS questionnaire was developed by Haher *et al* comprising 24 items[13] and later modified to include 22 items (SRS-22).[14 15] The population involved in these studies had a mean age that was older than AIS (25 years old, ranging 19–34 years), and therefore, may not be truly representative of AIS. Additionally, the mental health domain includes some questions from the SF-36 survey,[16] which was designed for an adult population, and is a generic rather than condition-specific measure. Further, the SRS-22 has reported ceiling effects (20%–44%),[14 17] which undermine its reported content validity and reliability.[8]

Using the International Classification of Functioning, Disability and Health (ICF), AIS reported limitations in their functioning.[6] The SRS-22 does not include items about the cardiovascular system, weight management or leisure, all of which are considered important to AIS.[6] These findings raise doubt as to the appropriateness of the SRS-22 and its revised version (SRS-22r) of this discrete population, and highlight the need for a content validity study of the SRS-22r in an English-speaking population to assess its suitability.

Our recent systematic review of measurement properties of physical functioning outcome measures used in AIS, shows that the SRS-22 is a widely used PROM and has been adapted and translated into more than eleven languages.[11] The common use of the SRS-22r may suggest acceptance within clinical and research practice. However, it is necessary to document its content validity with qualitative interviews from the population of interest with diverse characteristics to ensure that different perspectives of patients are fully captured within the PROM.[8] For adolescents, it is essential that a PROM is relevant to their age group and not just a use of adult measures,[18] considering their developmental stage and unique emotional and social characteristics.[18]

Although a PROM provides important information from a patients perspective, it might be influenced by a patient's perception of change,[19] and other factors such as pain and psychological stress, which often reported in this population.[4 20–22] The body structure and function measures, such as range of motion gives indication about the dysfunction in structure or function, but it fails to fully capture the functional limitations.[19] Conversely, performance-based outcome measures (eg, walking speed) may achieve a reproducible and unbiased assessment of function.[19] There is a preference in the literature towards using a PROM compared with performance-based outcome measure. Furthermore, studies that evaluate the measurement properties of these outcome measures were relatively limited, which may limit its use in AIS.[11] Thus, as well as understanding the content validity of the SRS-22r, to optimise the use of PROM in practice there is a need to understand perceptions of healthcare professional (HCP) who manage this specific population and explore the barriers and facilitators to use outcome measures.

Aim

To assess the content validity of the SRS-22r questionnaire with AIS and HCP. A secondary aim is to explore barriers and facilitators of HCP use of outcome measure in AIS.

Objectives

1. To elicit concepts that are most relevant and important to AIS.
2. To determine the relevance, comprehensiveness and comprehensibility of SRS-22r contents from the perspectives of AIS.
3. To determine the relevance, comprehensiveness of SRS-22r contents from perspectives of HCP.
4. To explore perceptions of HCP on the barriers and facilitators of using outcome measures in AIS.

METHODS AND ANALYSIS

Design and methods

This study will be reported in line with the COnsolidated criteria for Reporting Qualitative studies.[23] It will consist of semistructured interviews with AIS and a focus group discussion with HCP. The interpretive phenomenology analysis (IPA) will be used to explore and understand perceptions and experiences of AIS to their health condition and its associated treatment.[24] The IPA is an approach to collect and analyse qualitative data that seeks to understand the lived experience.[25] The IPA provide an open-ended approach which is needed for the concept elicitation of PROM items, to capture important aspects to patients.[26] To understand barriers and facilitators to use outcome measure among AIS, thematic analysis following Braun and Clarke framework will be used.[27]

The assessment of content validity of an existing PROM consists of both concept elicitation and cognitive debriefing. In concept elicitation, important concepts related to construct of the PROM are elicited from the target population and then mapped to the content of the existing PROM.[28] Meanwhile cognitive debriefing exploring participants understanding about three aspects of PROM, that is, relevance, comprehensiveness and comprehensibility of the items included in the PROM.[8] A flow chart of the study design is shown in (figure 1).

Participant recruitment and eligibility criteria

- Individuals should meet the following inclusion criteria to participate in semi-structured interviews: diagnosis of AIS by their respective physician (Cobb angle >25°); age 10–18 years old; and have access to a video/audio call platform. A Cobb angle of 25° has been chosen as the minimum curve size that may necessitate a change in management (eg, bracing, surgery) and going beyond observation and monitoring.[29]
- Exclusion criteria: individuals with other forms of scoliosis, and those who unable to speak English fluently.

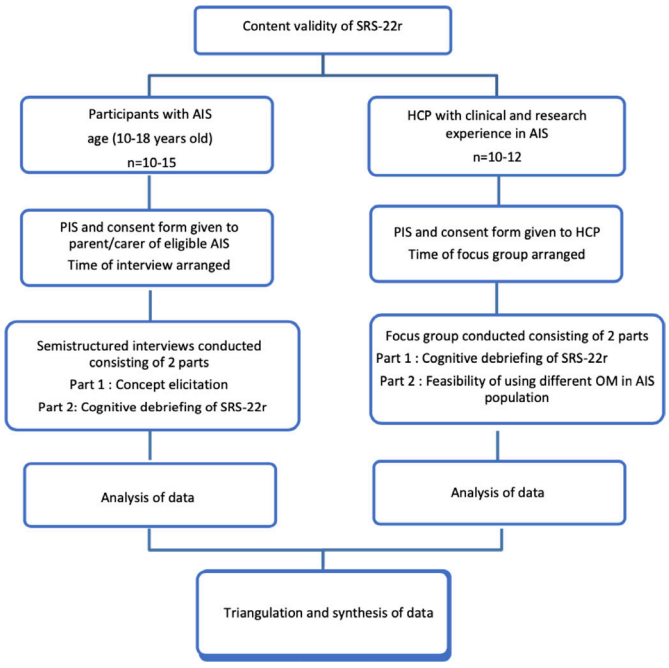

Figure 1 Study flow chart. AIS, adolescent idiopathic scoliosis; HCP, healthcare professional; OM, outcome measure; PIS, participants information sheet; SRS-22r, Scoliosis Research Society questionnaire-22 revised.

- A sample size of 5–25 participants was suggested for studies using phenomenology.[30 31] Thus, a purposive sample of n=15 participants was estimated to be sufficient to test the content validity of SRS-22r. Purposive sampling will be used to recruit participants, which is a method of identification and selection of participants who are experienced with the phenomenon of interest.[32] This is to ensure diversity in the sample in terms of age-categories, gender, ethnicity, different curve severity (mild, moderate and sever curves), that could be managed through observation, bracing and surgery. Those who treated with surgery would be sampled to recruit individual at different surgery status (eg, 3 months, 6 months, 1 year). This approach will enable a wide range of experience and opinions to be explored.[28 33]
- It has been recommended when examining the content validity of a PROM, data collection to be continued till point of saturation, to ensure that the items in the PROM appropriately represent the content of the concept.[7] Sampling will continue until data saturation is achieved, and whereby no new concepts emerge from participants' interviews or are considered as missing during the cognitive interviews.[28]
- Participants will be identified by a research nurse and the study will be outlined with them. Those who show interest in the study will be given an age relevant participant information sheet (PIS). Then, their parent/carer will be contacted by the lead researcher to confirm eligibility, discuss the PIS, answer any questions about the study and arrange the time of the interview.
- Clinicians who are treating AIS (physiotherapists, spinal surgeons, nurses), or individuals who have research experience in AIS will be invited to participate in a focus group discussion (expected n=10–12). We anticipate that two focus groups will be sufficient to fulfil the aims and objectives of the study.[34]

Study settings

Participants for the interviews and the focus group will be recruited from The Royal Orthopaedic Hospital NHS Trust, Birmingham, UK (figure 1). Both interviews and the focus group will be conducted virtual via Zoom/Microsoft Teams or by a phone call if video calling is not possible. A parent/carer or an adult family member will be asked to be present with child participants <16 years old throughout the interview. However, to ensure that the interview is reflecting the child's perspective, they will be asked to not actively participate in the interview unless invited to do so to lend support.

In instances where the parents/carers are not able to present with their child, the interviewer (SA) will make sure that the child is comfortable/happy to conduct the interview without their parent. The interview will be terminated if the child is unwilling to do so. The interviewer (SA) has both DBS check and safeguarding training to work with children. The timing of the focus group discussion will be selected at the convenience to all HCP participants.

Data collection and procedure

Objectives 1 and 2: semistructred interviews

The semistructured interview will last approximately 60–90 min, and it will adhere to PROM development format,[28] consisting of concept elicitation and cognitive debriefing.[8] The concept elicitation aims to elicit key concepts related to the influence of spine deformity on adolescents' QoL, while the cognitive debriefing aims to gather feedback on the content of the SRS-22r, including relevance, comprehensiveness and comprehensibility.[8 35] As well as exploring if there are any additional/important areas that need to be covered in the SRS-22r, participants will be invited to raise new topics and/or issues during the interviews.[28]

The topic guide (online supplemental file 1) was developed using existing evidence,[33] as well as perspectives of AIS through patient and public involvement. Additionally, the ICF framework[36] has been used to ensure all important aspects of the life of adolescents are covered. The topic guide is age-relevant and will be piloted with an AIS ahead of the main study to identify areas that do not flow easily or may confuse participants.[7] The topic guide consists of open-ended questions and it is written in way that allows participants to provide detailed information with unlimited responses.[7] The topic guide will be modified when new themes are discovered from the completed interviews.[33]

Objectives 3 and 4: focus group

HCP and researchers will be invited to join a focus group discussion, which will last approximately 60–90 min. It will consist of two parts, first to evaluate the content validity of SRS-22r and second to explore barriers and facilitators to the use of PROM for AIS. The topic guide (online supplemental file 2) has been developed and will be piloted ahead of the main study.[7]

Research team and reflexivity

Semistructured interviews will be undertaken by the chief researcher (SA). She is an experienced musculoskeletal physiotherapist with experience of working with adolescents. The focus group discussion of HCP will be led by an experienced musculoskeletal physiotherapy researcher with specialism in spinal research and experience in conducting qualitative research, as well as involvement of a spinal surgeon with experience working with AIS, and involvement of (ER) as Patient and Public Involvement (PPI). The lead interviewer for the interviews will be present as an observer and she will take field notes. Although no specific relationship will be established prior to the commencement of the interviews or focus group, participants will be informed about the professional background of the interviewer and that the study is part of a PhD thesis.

Data management and data analysis

Demographic and clinical information of participants will be collected prior to the interviews and focus group discussion which will then be used to characterise the sample. Interviews and the focus group will be audio recorded and transcribed verbatim. The transcripts will be emailed to participants or their parent/carer to enable member checking and allow any further details to be added. Participants will be given 2 weeks to make any alterations or suggest changes. The interviewer (SA) will take supplementary field notes during the interviews and focus group discussion to allow data triangulation. A saturation table will be used to document data saturation. The information elicited from interviews will be arranged by concept code.[28 37] Further, the depth of analysis will be evaluated using a code book.[28]

Coding of the first interview will be performed by two researchers (SA and NRH) to develop a coding plan and to ensure that researchers concur in coding. The lead researcher will then code the remaining interviews independently. Any new themes or codes arising from the transcripts will be reviewed by coders, for every 2–3 transcripts coded.

Qualitative interview data will be analysed according to a four-stage approach of IPA[38] :

Stage 1: Multiple reading and making notes. The initial stage will involve close reading of the transcripts multiple times. The researcher will then make notes about her observations and reflections about the interview experience.

Stage 2: Transforming notes into Emergent Themes. Notes from initial stage will be transformed into emerging themes. Preliminary themes will then be presented and discussed within the research team.

Stage 3: Seeking relationships and clustering themes. The emerging themes will be grouped together in clusters.

Stage 4: Production of summary table. Themes will be presented in a summary table with verbatim extract and it will be subsequently discussed with the research team.[38 39]

Themes that are generated from the analysis will be used as codes that will then be mapped to the content of the SRS-22r.[28]

Qualitative data produced from focus group discussion with HCP will be analysed using the Braun and Clarke 6-step process.[27]

1. Familiarise yourself with the data.
2. Generate initial codes.
3. Searching for themes.
4. Reviewing themes.
5. Defining and naming themes.
6. Producing the report.[27]

Data storage, access and disposal

Digital audio recordings of the interviews and the focus group will be uploaded securely and transcribed by the approved service provider. Participants' data will be kept on a secure, password protected, database on the site at the University of Birmingham for 10 years, accessible only to the research team. It will be kept in accordance with General Data Protection Regulation, the Data Protection Act 2018 and University of Birmingham's research governance framework.

Patient and public involvement

This study was conceived directly because of gaps identified in a systematic review of physical functioning outcome measures among AIS.[40] The protocol of systematic review was informed following discussions at a patient and public involvement meeting at the Centre of Precision Rehabilitation for Spinal Pain at the University of Birmingham. The PPI representative is a part of the study management group (comprise all coinvestigators involved in the design of the study, interpretation of the study and identification of the participants). Their feedback has been sought on the study protocol, the topic guide as well as the PISs and consent forms. Further, they will be involved in data analysis/interpretation and study findings through provision of a plain English summary.

Implications of this study

The AIS is a common spinal deformity that can significantly affect the adolescents QoL.[6] It is important that the PROM used for evaluating their QoL has sufficient content validity.[8] Adolescents comprise a unique population and a PROM should be relevant, comprehensible and capture all areas which are relevant and important to them.[18] A qualitative study with AIS is, therefore, needed to understand their experiences with their health

condition and its management, which then allows an evaluation of the SRS-22r contents. Findings from this study will provide important evidence on the content validity of SRS-22r, which will build confidence in the PROM findings[41] and further support its use in practice and for future research.

Ethics and dissemination

The Health Research Authority and Health and Care Research Wales approval has been granted (IRAS 289888). AIS participants will be advised that participation in study will not affect their current and future healthcare. Minimal risk is associated with this study. Informed consent from children >16 years old, and informed consent from the parent/carer, along with assent from the child <15 years old will be obtained prior to inclusion in the study. The study findings will be presented without identification of any study participants and any protocol amendment will be documented. Findings will be disseminated through publications in peer-reviewed journals as well as international and national conference presentations.

Author affiliations
[1]Centre of Precision Rehabilitation for Spinal Pain, School of Sport, Exercise & Rehabilitation Sciences, University of Birmingham, Birmingham, UK
[2]Physical Therapy Department,Faculty of Applied Medical Science, University of Tabuk, Tabuk, Saudi Arabia
[3]Spinal Unit, The Royal Orthopaedic Hospital, Birmingham, UK
[4]School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, UK
[5]Department of Acute General Medicine, Oxford University Hospitals NHS Foundation Trust, Oxford, UK
[6]School of Physical Therapy, Faculty of Health Sciences,Western University, London, Ontario, Canada

Twitter Deborah Falla @Deb_Falla, Alison B Rushton @abrushton and Nicola R Heneghan @HeneghanNicola

Contributors All authors conceptualised and designed the protocol. SA is a PhD student and NRH (lead supervisor), ABR and DF are supervisors and AG is a spinal surgeon. SA drafted the initial manuscript with NRH, ABR, DF and AG providing guidance on design, topic, methodology and analyses. ER acted as patient and public involvement representative, contributing to the design of the study. All authors reviewed and commented on each draft of the protocol. All authors have approved and contributed to the final manuscript.

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ORCID iDs
Samia Alamrani http://orcid.org/0000-0003-4099-8381
Deborah Falla http://orcid.org/0000-0003-1689-6190
Alison B Rushton http://orcid.org/0000-0001-8114-7669
Nicola R Heneghan http://orcid.org/0000-0001-7599-3674

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