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Involving patients and clinicians in a pilot randomised clinical trial of spinal manual therapy versus nerve root injection for lumbar radiculopathy: protocol of a patient and public involvement project

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ABSTRACT

Introduction A patient and public involvement (PPI) project will be embedded within the SALuBRITY pilot trial, a two parallel group, double sham controlled, randomised clinical trial. The study aims to compare the effectiveness of spinal manual therapy and corticosteroid nerve root injections, two methods commonly used to treat patients with lumbar radiculopathy. We aim to gather patients' and clinicians' perspectives and involve them in decisions related to the research question and objectives, proposed trial recruitment processes and methods, and proposed outcome measures.

Methods and analysis A small group of patients with lived experience of lumbar radiculopathy and primary care clinicians with experience in the treatment of patients with lumbar radiculopathy are involved. An initial kickoff event will prepare and empower the advisors for involvement in the project, followed by semistructured patient group and one-on-one clinician interviews. We will follow the Critical Outcomes of Research Engagement framework for assessing the impact of patient engagement in research. We will summarise and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs. Inductive and deductive thematic analysis will be used for the qualitative analysis of the interviews. Two surveys will be completed at different points along the trial to track the advisors' and researchers' experiences over the course of the PPI project. Any modifications to the SALuBRITY trial methods due to PPI inputs will be thoroughly documented and recorded in an impact log.

Ethics and dissemination The independent research ethics committee of Canton Zurich confirmed that ethical approval for this PPI subproject was not required. PPI results will be disseminated in a peer-reviewed journal and presented at conferences.

Strengths and limitations of this study

- ► This patient and public involvement (PPI) project is an important step for making research more relevant to end-users and facilitating research translation into clinical practice.
- ► Existing frameworks guide consultation and collaboration approaches and draw our attention to relevant outcomes to evaluate the impact of PPI activities.
- ► Patient and clinician advisors will be supplied with detailed information about PPI in general and the future trial to be empowered for their contribution to the project.
- ► Sample size is small and inadequate for quantitative analysis but allows a pragmatic qualitative approach and recognition of multiple individual realities.

INTRODUCTION

Patients' role in research has changed over the past decades from being study participants to getting engaged at different levels and in different stages of research.

The value of patient and public involvement (PPI) is increasingly recognised and prioritised by research regulators and funders,[1–3] academic journals,[4] and patient organisations.[5] The INVOLVE initiative, established in 1996 and funded by the National Institute for Health Research (NIHR) of the UK, was taken over by NIHR Center for Engagement and Dissemination in 2020 and defines public involvement as research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.[6] PPI represents an essential approach for keeping the research relevant to end-users (eg, patients and clinicians) and improving its translation into

real-world clinical practice by integrating patient and clinician perspectives on the relevant research topic.

Back-related leg pain affects about 200 million people worldwide, and was estimated to account for up to 35 million years lived with disability in 2017.[7] Lumbar radiculopathy—arising from lumbar spinal nerve root compression or irritation—is characterised by low back pain (LBP) that radiates down the leg in a lumbar nerve distribution.[8] With increased pain and disability, people suffering from back-related leg pain have poorer prognosis, quality of life and an increased use of health resources compared with people with LBP alone.[9] Spinal manual therapy (SMT) and corticosteroid nerve root injection (NRI) are two common conservative treatment methods in routine clinical care, but there is uncertainty regarding their effects. To assist patients, clinicians and policy-makers with decision making on the treatment of lumbar radiculopathy based on high-quality evidence, the SALuBRITY pilot trial—a two parallel group, double sham controlled, randomised clinical trial—is being developed.

PPI in the development phase of a clinical trial can help to identify possible challenges in the collaboration of researcher with patients at an early stage, with all involved people facing beneficial impacts. Researchers profit from extended funding, better enrolment rates,[10 11] and increased trust and advocates within the community under research.[12] Patients describe empowerment, increased knowledge and confidence, which emphasise the wide societal benefits and the potential for research to act as a positive force in society.[12] In recognition of these benefits—ultimately leading to improved quality and relevance of the research being conducted—we will carry out a PPI project nested in the SALuBRITY trial, aiming to improve the quality and relevance of the future trial.

Our goal is to enhance the quality of care and quality of life for patients with lumbar radiculopathy, which will be achieved in collaboration with patients and clinicians, whose lived experiences and expertise offer invaluable insights into lumbar radiculopathy and its treatment. Our general objectives are (1) to gather patients' and clinicians' perspectives and involve them in research discussions and decisions and (2) to assess the impact of PPI on the future SALuBRITY pilot randomised clinical trial investigating SMT and NRI in patients with lumbar radiculopathy. Specifically, we aim to answer the following questions:

- Is the trial's main question and objective important and relevant to patients with lumbar radiculopathy and primary care clinicians of patients with lumbar radiculopathy?
- Are the recruitment processes and proposed methods for the clinical trial acceptable and sensitive to potential participants and clinician collaborators?
- Are the proposed trial outcomes relevant and important to patients with lumbar radiculopathy?
- Are the language and content of trial information appropriate and accessible to participants and clinicians?
- What is the impact of PPI on the relevance and quality of the SALuBRITY pilot randomised clinical trial?

METHODS AND ANALYSIS

Study design

We will involve a small group of patients (n=3–6) with lived experience of lumbar radiculopathy and primary care clinicians (n=3–4) that care for patients with lumbar radiculopathy. The different levels of involvement are distinguished, based on the flow of information between patients and the public, and professionals of the research team.[13] We will use consultation and collaboration approaches as qualitative methods. Consultation is defined as the collection of information from patients and the public, usually with no back-and-forth interaction with the research team and shows potential for gathering the view of a larger group of individuals. Collaboration represents a bidirectional exchange, where decisions about research are shared and it requires commitment, openness and flexibility for all involved parties.[6 13] Group meetings and one-on-one interviews will be organised to discuss the acceptability, sensitivity and relevance of the proposed methods, trial outcomes, and information in the context of potential trial patient participants and primary care clinician collaborators. To gather feedback on the language and content of patient trial documents, additional patients will be recruited one after another to participate in a think-aloud process until no new feedback is generated (*a priori* sample estimate, n=2–4).

Patient and clinician advisors

Purposeful sampling will be used to involve patient and clinician advisors for this project.[14] This is a technique used in qualitative research, to gather individuals most knowledgeable about a topic of interest and supporting the intention to achieve depth of understanding until saturation is achieved. Patient advisors will be current or former patients of the chiropractic medicine polyclinic at Balgrist University Hospital in Zurich, Switzerland, or from other internal or external collaborating clinicians. Eligibility criteria are age between 18 and 65 years, lived experience of lumbar radiculopathy, and willingness to be involved as a patient advisor. Patients will be considered if they received at least one of the treatment interventions of interest (SMT or NRI), but patients who are experienced with multiple treatment modalities (such as chiropractic treatment, physiotherapy, massage, NRI, or surgery) will be preferred. Clinicians at the chiropractic medicine clinic at Balgrist University Hospital will be informed about the PPI project and will ask eligible patients for permission to be invited by the PPI team. On agreement, the potential patient advisor will be contacted and invited by a project lead for further information. Primary care clinicians in the surrounding region of Zurich will be contacted and informed about the PPI project. They will be considered eligible for involvement in this PPI project if they have experience providing primary care to patients with lumbar radiculopathy and are willing to be involved

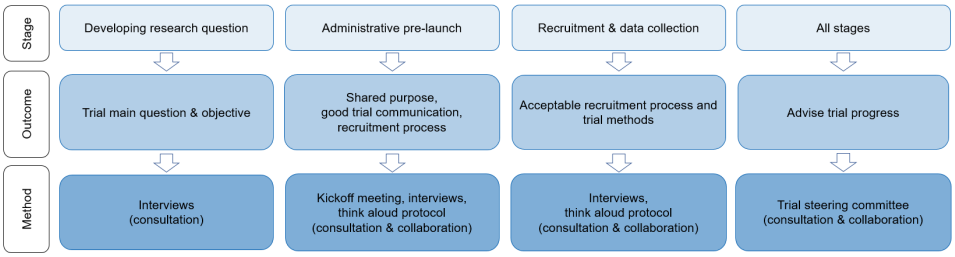

Figure 1 Stages, outcomes and methods of involvement.

as a primary care clinician advisor. Patient and clinician advisors will not be incentivised to participate through any offer of monetary or other compensation for their involvement, but a small token of appreciation (gift card of small value) will be provided in thanks for their involvement after completion of the PPI activities.

Stages of involvement

The Critical Outcomes of Research Engagement (COREs) framework was designed for improving the quality and efficiency of research and maximising its societal impact.[15] COREs will inform our PPI study design by drawing our attention to the ways in which patients and clinicians can be engaged during each of the specific research stages as well as relevant outcomes to evaluate the impact of PPI activities. Patient and clinician advisors will be involved mainly through consultation and collaboration approaches to gather their insights regarding recruitment strategy, patient and clinician information documents, aspects of trial methods, and outcome measures. Additionally, a patient advisor will be involved on the trial steering committee. Figure 1 provides our adapted CORE framework with details on advisors, types of involvement, desired outcomes and methods used, summarised by research stages.

PPI activities

Kickoff meeting

Patient and clinician advisors will meet for an initial, virtual kickoff event. The first part will provide information on how clinical research and PPI projects work and will clarify expectations of all involved parties. After splitting up into separate patient and clinician advisory groups, the second part of the kickoff event will familiarise the advisors with the planned PPI project tasks (see online supplemental appendix A). The kickoff event will facilitate the establishment of rapport among the advisors and the PPI project team, and also prepare and empower the patient and clinician advisors for involvement on the project. After the kickoff meeting, the expectations of the patients and clinicians will be summarised and fed back to all participants as a shared purpose statement to ensure accurate interpretation. Additionally, clinician information trial documents will be sent to the clinician advisors to give them enough time to review and prepare for their interviews.

Individual and focus group interviews

A patient advisory group meeting and individual semi-structured one-on-one interviews with clinician advisors will be conducted virtually. Brief vignettes covering key PPI topics will be used to introduce topics and initiate consultation and collaboration discussions. Open questions will be used to initiate discussions, with more structured questions prespecified, in case recalibration of the discussion is needed (see online supplemental appendix B). Each interview will be conducted by three members of the research team. One of them will take the lead as the moderator who will ask questions and guide discussion. The assistants will record the interview and take comprehensive notes, with any discrepancies in notes resolved by consensus.

Think-aloud method

A think-aloud approach, in which advisors speak their thoughts aloud while performing a task, will be used to collect feedback on patient trial information documents.[16] The documents will be provided at the beginning of the meeting, and the patient advisors will be asked to verbalise their thoughts while reading it aloud. An assistant will take notes to contribute to the digitally recorded material. Discussion about ambiguous sections will take place after completion of the task. An instruction guide is provided in online supplemental appendix C.

Data collection and analysis

Demographics of all advisors will be collected by means of a short electronic questionnaire. Communication with patient advisors will be in German (eg, interviews, member-checking) as this is the primary language in the region and the data collected will be subsequently translated to English. As almost all clinicians in Switzerland are proficient in English (global academic language), clinician advisors will be interviewed in English. Instead of verbatim transcription, we will summarise and feedback PPI content to the patient and clinician advisors during a member-checking process to ensure accurate interpretation of patient and clinician inputs.[17]

For the qualitative analysis of the interviews, thematic analysis will be performed according to Braun and Clarke's six-phase guide: (1) familiarisation with data, (2) generating initial codes, (3) searching for themes, (4) reviewing themes, (5) defining and naming themes,

and (6) producing report.[18] The vignettes (online supplemental appendix B) will provide guidance and represent key questions we aim to code around for the deductive approach of the thematic analysis. At the same time, we will use open coding which allows inductive thinking, to gather a broader view on the topic of interest and enable recording of unsolicited themes. Patient and clinician interviews will initially be coded separately. As both advisory groups follow similar interview guides, they will be mapped onto one another, exploring how codes and themes will manifest across both groups. Representative patient and clinician quotes will be identified.

Any modifications to the SALuBRITY pilot or future main trial methods as a result of PPI inputs will be thoroughly documented and recorded in an impact log (see online supplemental appendix D). In order to track the advisors' and researchers' experiences over the course of the PPI project, two surveys are meant to be completed at different time points along the trial.[19] The first will be delivered after the kickoff meeting, the second after completion of all participation activities. The surveys are adapted to our project and provided in online supplemental appendix E. Descriptive statistics will be used to analyse the survey data.

The Guidance for Reporting Involvement of Patients and the Public (GRIPP2) reporting checklist will be used to enhance the quality and transparency of the PPI reporting.[20]

PPI in the design of this protocol

This is a protocol for a PPI project. No patients or members of the public were involved in the design of the protocol.

ETHICS AND DISSEMINATION

The independent research ethics committee of Canton Zurich confirmed that ethical approval was not required for this PPI project. The active involvement of patients or members of the public does not generally raise any ethical concerns for the people who are actively involved, as they are not acting in the same way as research participants. They are acting as specialist advisers, providing valuable knowledge and expertise based on their experience of a health condition or public health concern. Therefore, ethical approval is not needed for the active involvement element of the research, where people are involved in planning or advising on research.

Patient and clinician advisors will provide important end-user lived experience insights and advice—an important step for making research more relevant to end-users and improving its quality. This may facilitate its translation into clinical practice. Our dissemination plan for the PPI project will include publishing our results in a relevant peer-reviewed journal and presenting at conferences.

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