Appendix B – Interview Guide

Patient Advisors Interview Guide

Vignette 1: Research question
Introduction:
The research question and primary objective of the future main trial was presented in detail during the kick-off meeting and is briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:
What are your thoughts on the importance and relevance of the trial's main question?

"To compare SMT with NRI in patients with lumbar radiculopathy in terms of pain impact at 12-wees after randomization and assess outcomes over a 1-year follow-up."

Specific guiding questions:
None

Vignette 2: Proposed methods
Information about proposed methods with the double sham controlled, randomized study design presented in detail during the kick-off meeting.

a) Study design
Introduction:
The principle and purpose of the two study arms (group A receiving active SMT and sham NRI, group B receiving active NRI and sham SMT) as well as the importance of blinding of patients and managing clinician is presented again.

Opening question:
What are your thoughts on the proposed randomised double sham design?

Specific guiding questions:
- Thoughts on the principle of random allocation of the two trial active interventions?
- Thoughts on the principle of blinding of patients to the active intervention?
- Thoughts on the principle of blinding of the managing clinician?
- Thoughts on the treatment by another, "foreign" clinician?

b) Recruitment process and timings
Introduction:
The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again.

Opening question:
What do you think about the proposed recruitment processes and timings?

Specific guiding questions:
- Thoughts on the proposed timings from primary care visit to initial trial telephone screen, to trial eligibility screening visit, to first treatment visit? Assumption 0-5days.

c) Discontinuation of pain medication
Introduction:
Rationale for discontinuing pain medication for 12-24 hours prior to each study visit is discussed.

Opening question:
What are your thoughts about the request for patients to discontinue their pain medication prior to trial study visits?

Specific guiding questions:
- Would you personally be willing to forego your pain medication during a 0-24 hour period if you were participating in such a trial? Why, or why not?

Vignette 3: Trial outcomes
a) Primary outcome
Introduction:
Information about proposed outcomes is presented to the patient advisors. The focus is put on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), which is presented in detail. Other secondary patient-reported outcomes (i.e. physical function, quality of life, patient satisfaction with care, pain medication use, work disability, healthcare use) are presented briefly to the advisors to provide them enough information to discuss the relevance and importance of the proposed primary outcome.

Opening question:
What are your thoughts about the trial's proposed outcomes?

Specific guiding questions:
- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?
- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?
- Do you think it is important to ask for the intensity of the pain?
- Can you think of other relevant outcomes that we have not covered yet?

b) Clinical course as measured by weekly SMS messaging
Introduction:
The idea of measuring clinical outcomes by weekly SMS messaging is presented to the patient advisors.

Opening question:
What are your thoughts about weekly SMS messaging as a way to measure primary outcomes?

Specific guiding questions:
- Would you feel comfortable with this way of measuring clinical course?
- Do you have experience collecting data this way?
- How optimistic are you about your ability to reliably provide data about clinical outcomes via SMS?

Clinician Advisors Interview Guide

Vignette 1: Research question
Introduction:
The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:
What are your thoughts on the importance and relevance of the trial's main question?

Specific guiding questions:
- Could you imagine that the results of this trial would influence your clinical practice?
- Where do you see gaps in evidence that would be useful to guide your clinical practice and
treatment of patients with lumbar radiculopathy?

Vignette 2: Proposed methods
a) Recruitment process and timings
Introduction:
The process from recruitment, screening, randomization, to the start of treatment is briefly outlined again. The trial clinician information form was provided to all clinician advisors after the kick-off group meeting to give them enough time to read and review it. The form contains a brief summary of the trial itself, information about the eligibility criteria, and the instruction about the referring process of potential participants. Different options/processes of referring mechanisms are presented.

Opening question:
What are your thoughts on the proposed recruitment processes and timings?

Pre-specified questions:
- Thoughts on improvements of the referring process?
- What are your thoughts on the clinician recruitment information package?

b) Discontinuation of pain medication
Introduction:
The research question and primary objective of the future main trial were presented in detail during the kick-off meeting and are briefly reviewed. For this vignette, a consultation approach is mainly taken, as background evidence and past clinical research clearly and compellingly points to the knowledge gap that the SALuBRITY trial aims to fill.

Opening question:
What are your thoughts about the proposal to have patients discontinue their pain medication 0 to 48 hours prior to study visits?

Specific guiding questions:
- What are your thoughts about the proposal to have patients discontinue their pain medication 12 to 24 h prior to study visits?

Vignette 3: Trial outcomes
a) Primary outcome
Introduction:
Information about proposed outcomes, with the focus on the primary clinical outcome of the trial (i.e. pain impact, measured with the 3-item PEG scale), is presented again.

Opening question:
What are your thoughts about the trial's proposed primary clinical outcome?

Specific guiding questions:
- Do you think pain impact (measured with the PEG scale) is a relevant and important primary outcome?
- Thoughts on the most relevant pain location to assess pain impact (i.e. back pain, leg pain, or overall pain)?

b) Non-inferiority margin
Introduction:
The non-inferiority approach aims to determine whether SMT is non inferior to NRI in terms of pain impact. The minimal clinically important difference (MCID) in most trials in literature regarding the pain numeric rating scale (NRS), is 1 point on a scale between 1 and 10. Proposed is a non-inferiority margin of 0.75 points on the PEG scale, meaning 75% of the MCID.

Opening question:
Do you think a between-group difference of up to 0.75 points on the PEG scale is ignorable?

Vignette 4: Referral Network
Introduction:
One of the main challenges of the SALuBRITY trial is the recruitment of the participants. Recruitment is taking place at primary care practices and through Balgrist internal network.

Opening question:
Do you have other ideas for recruitment of GP referral network?