

**Title:** An exploration of the experiences and educational needs of patients with Failed Back Surgery Syndrome receiving spinal cord stimulation.

**Running title:** The patient experience of undergoing SCS

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**Sources of Financial Support**

This study was funded by Medtronic Europe Sarl

**Authorship Statement**

All authors meet the ICJME criteria for authorship

**Conflict of Interest Statement**

This study was funded by the Medtronic Europe Sarl. Two of the authors (CR and DM) are named inventors on a patent application for a novel device that delivers sensory discrimination training. The device could be used in the treatment of people with chronic pain. The remaining authors have no conflicts of interest to declare.

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## **ABSTRACT**

**OBJECTIVE:** To explore the experience of spinal cord stimulation (SCS) for patients with failed back surgery syndrome (FBSS).

**METHODS:** Adults with FBSS referred for SCS underwent semi-structured interviews at three time points: before their SCS trial, after the trial, and three months after receiving the SCS implant. The face-to-face interviews were audio recorded, transcribed verbatim and analysed thematically.

**RESULTS:** Twelve adults (8 male, 4 female, aged 38-80yrs, pain duration 1-26yrs) were recruited. Six themes were identified; 1) What should I expect? 2) Varied Outcomes, 3) Understanding pain and this new treatment, 4) Experiences of the SCS journey, 5) Getting used to the device, and 6) Finding out what I need to know.

Participants' expectations were varied and the procedures were broadly viewed as minor surgery. Participants' expectations about SCS were not limited to pain relief and included reductions in medication, better sleep and increased physical activity. Participants' understanding of pain and how SCS purports to work was limited. Throughout the process practical challenges were identified such as the surgical wound management and battery recharging. Participants received information from multiple sources and identified a range of key information needs including a quick-start guide on how to operate the device and a list of dos and don'ts.

**CONCLUSIONS:** Overall, participants' understanding of SCS was limited. The value participants placed on understanding of the process varied markedly. A list of practical informational needs has been identified. Bespoke, user-friendly, informational tools should be developed from this list to enhance the patient experience of SCS.

**KEY WORDS:** Spinal cord stimulation; Neuromodulation; Failed back surgery syndrome; Qualitative research; Patient experience.

## **INTRODUCTION**

Clinical trials demonstrate benefit from spinal cord stimulation (SCS) for patients with Failed Back Surgery Syndrome (FBSS) (1-4). Further development of optimal methods of delivery of SCS would benefit from qualitative studies of patient experience. Few qualitative studies have explored SCS from the patient perspective (5-7). Only one study has explored the experience of patients who had received SCS (5) rather than those awaiting treatment (6, 7).

Sparkes et al. (2012) (5) explored the experiences of 13 people with chronic pain one year after receiving SCS. Participants reported deficiencies in the information provided prior to receiving the intervention. Furthermore, some patients felt they had received contradictory information and reported unexpected experiences. They felt that enhanced information regarding expectations about the trial procedure and access to an expert patient who had previously undergone the procedure would have minimised these issues and improved their overall experience. A limitation of this study was the lack of detail regarding the specific information wanted. Without such detail it is difficult to make specific suggestions for the enhancement of the information provision. Additionally, patients were interviewed one year after receiving SCS, introducing considerable potential for recall bias. Finally, the patients were a heterogenous group of chronic pain patients with pain in different areas, thus the specific experiences of patients with FBSS, who make up a large proportion of SCS patients, were not investigated.

The aim of this study was to explore the experience of SCS for patients with FBSS. There was particular emphasis on exploring the educational needs of patients, their expectations and experiences of SCS, their perceptions of the trial period and the role it played in their decision making about progression to SCS implantation.

## **METHODS AND MATERIALS**

### **Participants**

We used purposive sampling to recruit 12 participants including men and women from a range of ages and those designated for different types of SCS (e.g. high and conventional frequency stimulators). The inclusion criteria were: aged  $\geq 18$  years; experiencing persistent pain for  $\geq 6$  months with a Visual Analogue Scale (VAS) of  $\geq 5$ cm indicative of moderate-to-severe pain (8); diagnosed with FBSS with no options of further surgical interventions; clinically appropriate candidate for SCS. The exclusion criteria were: unable to speak and/or understand English as the study involved in-depth semi-structured interviews; lack of capacity to provide informed consent; any clinical contraindication to SCS.

### **Recruitment and ethics**

Participants were recruited from The James Cook University Hospital, a tertiary centre in the North East of England. Patients were informed about the study when it was decided that they would receive SCS and they gave their written informed consent at the first research interview. The study received ethical approval from Teesside University's School of Health and Social Care Research Governance and Ethics committee (Reference number 012/05) and the South Central - Berkshire Research and Ethics Committee of the NHS Health Research Authority (15/SC/0182).

### **Data collection and analysis**

In this qualitative study, face-to-face semi-structured interviews were conducted (by SJ) with each participant at three time points either at the hospital or patient's home: prior to receiving

the intervention, after undergoing the trial procedure, and 2-3 months after receiving the implant. If the participant did not receive an implant the final interview occurred 2-3 months after the trial. Interviews lasted approximately 1 hour, were audio-recorded and transcribed verbatim. The interview script is shown in Table 1. Transcripts were analysed thematically in keeping with the six steps proposed by Braun and Clarke (2006); data familiarisation (reading and re-reading the transcripts), generation of initial codes, searching for themes, reviewing themes to generate a thematic map of the analysis, refining/defining and naming themes, and production of the final report (9). Two members of the research team (HE, CR) read the transcripts in full and identified key themes within the participants' accounts, to give a detailed description of their experiences. These were then discussed amongst the wider research team to shape and refine the themes. Also recorded were age, sex, pain duration, and pain levels at all three interview points using the pain Visual Analogue Scale (VAS) (10).

**Insert table 1 here**

## **RESULTS**

Twelve participants (Table 2) were interviewed between August 2015 and May 2017. Nine had a SCS device implanted permanently and three did not, after failure at trial level. Pain scores at first (T1), second (T2) and third (T3) interview were 2.5 to 8.5 ( $6.3 \pm 2.0$ ) [range (mean $\pm$ SD)], 0 to 9.5 ( $4.5 \pm 3.1$ ) and 0 to 9.5 ( $4.6 \pm 3.2$ ), respectively. Six themes emerged from the data: 1) What should I expect? 2) Varied Outcomes, 3) Understanding pain and this new treatment, 4) Experiences of the SCS journey, 5) Getting used to the device, and 6) Finding out what I need to know.

**Insert table 2 here**

### **What should I expect?**

Prior to the intervention, participants' expectations were quite broad, including pain relief, a reduction in pain medication, an end to hospital appointments, better sleep and a return to normal.

*014 – “if it can reduce it [leg pain] to the level that I either don't notice it or I can cope with it, I'd be happy” (T1)*

Some participants had no outcome expectations at all, or didn't permit themselves such expectations. Patients wanted more definitive guidance on potential outcomes such as the chance of success.

*008 – “Well it's just I wanna know what they're going to do and what the success rate is going to be” (T1)*

This presents clinicians with a challenge. A lack of definitive data upon which to provide estimates of success rates is combined with a need to not invoke false hope, balanced against the need not to foster pessimism as lower expectations are associated with poorer outcomes to interventions (11-13). There appeared to be a consistent message delivered to participants that all patients are different, and responses vary. Such a response may be the most appropriate given the lack of clear evidence and the value placed upon honest communication and realistic expectation setting, previously reported in the FBSS literature (6).

Whilst participants expected some pain/discomfort from the operations, they expressed this as not being as bad as expected and were not unduly concerned about undergoing surgery. Contrastingly, patients conveyed a range of worries about the treatment and aspects of the process itself. One participant in particular (013) expressed concern after reading other people's experiences online.

*013 – “I joined a group on Facebook ... you see the ones that, a-have had it done and they, it hasn't worked and they put these photographs on and their back they're [exhale] just a mess ... there was one lady ... hers was in her stomach and ... it was sticking right out and [inhale], I thought I couldn't stand it-you could see the whole shape of the square and she was having to go back ... and I thought I just [exhale and laughs], I don't know if I can put up with that” (T1)*

The internet is a major source of medical information for patients (14); however, online searching for health information can increase anxiety (15) and lead to catastrophic explanations for their symptoms (16). Thus, signposting patients who use the internet to specific and credible sources of information online is warranted.

### **Varied Outcomes**

There were several positive outcomes of SCS treatment reported, broadly in keeping with pre-treatment expectations/wants including pain relief, reductions in medication, better sleep, increased activity and improved mood.

*004 – “But I definitely got pain relief in, in my leg, definitely and in my heels” (T2)*



007 – *“I walked without the stick and I haven’t walked... without the stick for twenty years” (T2)*

This coincides with quantitative studies reporting reduced pain (17), increased mobility (3, 18), reduction in medications (4) and improvement in mood (19, 20). However, not everyone reported pain relief or the magnitude of relief they expected. This highlights the variability in individual response to SCS, adding to the difficulty in creating a single set of information for patients before they start the process, in terms of what they will experience, their outcomes or any other information.

Participants reported side-effects of SCS, some of which were similar to those reported previously (21, 22). Perceived side-effects included altered toileting, dizziness (*I swirl*), excessive tingling, wound swelling/oozing/pain and infection. In our study, infection was only reported by one participant and had minimal impact on him.

002 – *“It’s just the swelling. If I could get rid of that bit there, I’d be happy with that. It’s a catch-22. I did tell her, since I’ve had it in, when I go to the toilet, it’s always runny” (T3)*

Three participants did not proceed to full device implant. These participants were considering their options including another attempt at SCS. Some felt that no further treatment options were available to them. These individuals reported a number of repercussions relating to the *failed* process, including increased use of pain medication; increased pain, unpredictable pain and disappointment.

008 – *“And I’m more or less doubling the amount of Tramadol that I’m taking. Not that I want to, I don’t want-I’d like to put them in the bin” (T3)*

### **Understanding pain and this new treatment**

All participants believed pain indicated a physical injury contextualised almost exclusively within a biomedical understanding of pain, attributing their pain to factors such as nerve damage and surgical scar tissue. This reflects the literature where the majority of patients hold a biomedical understanding of their chronic pain (23, 24).

004 – *“I’ve got nerve damage, definitely got nerve damage, definitely” (T1)*

Participants displayed only a limited understanding of the SCS trial process. Some wanted to know more about the different settings of the trial device and how the device was removed if they did not proceed to full implant. The majority of participants (11/12) regarded the trial as useful.

003 – *“No I think it’s a good idea to have the trial first. Because if you just went in and had the operation and you didn’t have any benefit, then you’d be disappointed” (T2)*

Some participants wanted a better explanation of their pain and SCS, but paradoxically also stated that they did not care so much about this but just wanted pain relief. A number of participants likened SCS to transcutaneous electrical nerve stimulation (TENS). However, participants were often unable to describe or explain how TENS worked either.

010 – I: *“How do you think the nerve stimulator actually works to change that pain? ... P: “Yep, yeah, I think the brain, brain gets the messages that I do not have pain there. So, so that when the brain gets that message, so I, I won’t have pain. Yeah. Well that’s the same as TENS machine isn’t it? The signals to the brain says, there’s no pain, there at all” (T1)*

Participants did show an understanding that SCS was a treatment to help manage pain, not cure it. This is encouraging as Sparkes et al. (2012) (5) found that understanding SCS as pain management and not a cure is important for participants’ expectations about what SCS will achieve.

### **Experiences of the SCS journey**

Participants’ experiences of the trial were quite disparate, reflecting unique patient journeys as well as variable operator technique. Some reported being asleep while others reported being awake during the procedure. Some reported practical wound related issues such as bruising, oozing, swelling and difficulties driving, whilst others reported no such issues.

003 – *“No. It was just my side that kept weeping. Where the wire was” (T2)*

010 – P: *“It [the wound] was very well padded as well, really well.” I: “And did it ooze very much or was it alright?” P: “No, no, no” (T2)*

The main concern in the SCS literature regarding wounds and their management post-surgery relates to infection (22, 25) and not practical management, discomfort, or impact on activities of daily living. All participants thought the trial was beneficial, except one, who due to his specific circumstances, went straight from trial to SCS implant within a single hospital stay and therefore wished, with hindsight, he had by-passed the trial, due to his positive outcome.

007 – *“In hindsight, I think ... I would have preferred the whole thing [Full SCS implantation] had gone ahead straight away.” (T3)*

All participants reported the procedures being relatively non-invasive and viewed their treatment this way throughout the process. This may be due to reflection on previously invasive surgeries they had received. This contrasts with the scientific literature which frequently considers SCS as an invasive treatment (26-28).

Participants experienced a range of thoughts and emotions. These ranged from feeling brave or nervous, to feeling worried they would not be given the implant if the trial was unsuccessful.

004 – *“It’s just waiting to see isn’t it whether he’ll give me it [full SCS implant] or not. That, that, that is my main...worry” (T2)*

Some participants were cautious about doing too much physical activity due to either their pain (prior to trial) or their treatment. Others were also self-conscious about their wound.

002 – *“Walked up the street, grabbed a loaf of bread and back down. Didn’t want to stop though, cos if I had stopped and it had started oozing out on to your T-shirt and that, it’s not very nice” (T2)*

Three participants did not proceed to full device implantation. Of particular note was one participant who experienced an adverse reaction to the trial stimulator. The trial stimulator produced an altered sensation (tingling), and whilst this sensation was considered a successful

intervention/sensation in others, in her case it was considered worse than the pain. The participant described it as an *attack* on her body and said that she would rather deal with the pain.

*010 – “but I actually felt, now when I really think of it I felt, there was something foreign thing attacking me all the time, because of the tingling, in the ou-er-yeah, that would have really made my mind go, you know I would have gone off my mind. But it was quite severe so, I’m really glad I came out of it without having the implant...with the, machine, put inside yeah” (T3)*

This exemplifies that SCS treatment is not a one-size-fits-all solution. Even when it produces the intended sensations this does not mean SCS will be acceptable to all who try it. Other participants reported no concerns regarding the tingling that the trial stimulator produced and did not speak of it negatively, suggesting they found it acceptable. De Vos et al. (2014) (27) states that the perception and appreciation of the tingling sensation (paraesthesia) varies amongst patients. In some cases patients report paraesthesia as a negative and in others it is reported as a positive (29).

### **Getting used to the device**

A number of practical issues were raised as important including concerns over how to carry around their trial device (and associated paraphernalia) and wound care.

*014 – “cos you can’t do anything you know you’ve got this big block attached to you, for your trial. And erm, the sleep with the trial unit. You know they you’ve got this big four inch by two inch block attached to you by wires, where, what do you do with it,*

*you know you've got it on a belt but it comes loose and...I ended up with it behind me once and I'd pulled it and turned it off so I had to turn it back on again quickly" (T3)*

Recharging the device was challenging for three of the participants (002/004/015), reporting varying degrees of difficulty with the mechanics of connecting the charging device and maintaining a good connection. However, most found this straightforward and integrated it into their everyday lives quite easily.

Internal placement of the SCS device was an issue for three of the participants (001/003/011) regarding where to place it and the impact this had on their daily lives. One participant could not wear tight trousers (jeans) as they would press on the internal device. Another stated the internal device pressed on their bladder and came into contact with the belt on their trousers.

*003 – "Yeah so if you sit forward, presses on your bladder and you're, you can't wait, you have to go straight away [laughs]" (T3)*

There was a varied approach to programming and use of the SCS device. Some participants had their device on continuously, whereas others used it when needed. Some seemed reluctant to alter the settings at all.

*003 – "so I only put it on when I've got the pain and then, when that wears off I turn it off" (T3)*

*004 – I: "But you basically have it on all the time through the twenty-four hours and is that the recommendation anyway." P: "Yes. Yeah. Yes, I've just asked her" (T3)*

*011 – "Never touched, never touched it. No, no they've, they set it, and that was it" (T2)*

### **Finding out what I need to know**

All participants received basic written information, including hospital leaflets and a manufacturer's booklet about SCS. Some participants also used other sources such as newspapers, magazines, internet or other (previous) SCS patients known to them. In keeping with previous work (5) some individuals wanted access to expert patients/peer support to provide an informal mechanism to ask questions, to alleviate anxieties or worries.

*014 – “If there was somebody that people could either contact or, see at the clinic like this, who's already had it done. Would be good. Cos obv-obviously there is questions you want to ask, erm, and there is things that the doctors don't tell you about” (T3)*

This service was available, but participants appeared unaware of this. It is possible this information was buried within the large body of information provided to patients.

Participants expressed contrasting informational needs with some wanting more information, while others did not. Many participants felt that it did not matter what they knew about pain, their treatment or potential outcomes in order for them to progress with the treatment.

*011 – I: “are you bothered, about knowing h-how it works?” P: No. Well it's...yes and no I mean, just it's er as long as I get that little bit ease, that's all I'm after.*

This linked in with the trust participants placed in hospital staff. All participants had enormous trust and faith in the staff, from people they first met at the hospital (receptionists, porters etc) through to their consultants.

*001 – I trust him [the surgeon] a million percent” (T2)*

This trust may be why they did not want (or need) to receive any further information, meaning that they were happy to take advice and treatment as given. A list of the different specific information needs identified by patients is presented in Table 3.

**Insert table 3 here**

## **CONCLUSION**

This study explored the experience of SCS for patients with FBSS. Six themes were identified; 1) What should I expect? 2) Varied Outcomes, 3) Understanding pain and this new treatment, 4) Experiences of the SCS journey, 5) Getting used to the device, and 6) Finding out what I need to know. Our results suggest that patients’ understanding of their pain and SCS is limited. However, the amount and depth of understanding that patients wanted varied considerably from person to person. Participants identified a number of key informational needs, many of a practical nature, such as a list of time appropriate do’s and don’ts. This list could be used to create informational tools to enhance the patient experience. Ideally these tools/resources would not be confined to written sources of information but could include timely access to information perceived as personally relevant (e.g. through a named contact or advice / helpline/ mobile application) as a form of informational care run in parallel with, and as an integral part of, the SCS process.

A strength of this study was that two researchers read all the transcripts to enhance the credibility of the analysis. Majority and minority opinions were reported rather than disregarding minority views to enhance the dependability of the data. Themes are supported by



quotes ensuring they are rooted in the data. Data saturation was achieved after interviewing 10 participants, though final participants were not discounted because of this and were analysed to include the full nature of their experiences. The study included three interviews per participant, providing 36 interviews, which presented us with a rich, real-time insight into the patient experience. This overcomes a key limitation of the only existing qualitative study to explore patients' experience of having received SCS where interviews occurred one-year post intervention (5). Participants included both males and females with a wide age range (38-80 years) increasing the transferability of the findings. In contrast, the study sample were English-speaking individuals living in the North East of England, thus the findings may not transfer beyond this setting. This is also the first qualitative study to interview patients who did not have an SCS device implanted post trial.

Regarding future work, this study has identified a range of educational and informational needs. A body of co-production work with patients is warranted to generate materials to address these needs, with a view to improving the patient experience. This information could be provided through various media, including a mobile application, which has the advantage that it can be easily adapted to the depth of information the patient wishes to receive. Future work could explore the influence of such material on the patient experience and investigate if it has an effect on outcomes and overall satisfaction.

In summary, participants' understanding of pain and SCS was limited. Paradoxically, patients reported wanting to know more whilst conveying the message that this knowledge mattered little to them as long as the treatment worked. Participants had varied expectations regarding what SCS would do for them. Their experiences of receiving SCS (including the trial) also varied markedly. Participants communicated a plethora of suggestions to fulfil their

educational needs related to practical issues they encountered during the entire process. Future educational materials should ensure that these suggestions are incorporated into comprehensive and user-friendly resources that can adapt to the information needs of the patient to enhance patient experience.

## **ACKNOWLEDGEMENTS**

The authors would like to thank all participants in the study for their time and dedication to the project. We would also like to thank Sharon Husband who was the patient representative on the study steering group and made a substantial contribution to the project.

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**Table 1: Interview Script**

1. What is your understanding of nerve related pain?
2. What is your understanding of SCS and its effects on pain?
3. Do you feel it is important for you to understand neuropathic pain and SCS?
4. What are your expectations of SCS? (1<sup>st</sup> interview)
  - 4a. What are your expectations of the trial? (1<sup>st</sup> interview )
  - 4b. Do you think your expectations of the trial were met, how has this changed your expectations about SCS? (2<sup>nd</sup> interview)
  - 4c. Do you think your expectations of SCS were met? (3<sup>rd</sup> interview)
  - 4d. What are your expectations for SCS in the longer term? (3<sup>rd</sup> interview)
5. What are your opinions on the information material you received on the trial/SCS?
6. Do you feel there is any information you would have liked to receive but did not?
7. What do you feel was the most important piece of information you received prior to receiving the trial/SCS?
8. Tell me about your experiences of the trial? (2<sup>nd</sup> interview)
  - 8a. Did you find the trial period useful in helping you decide about long term SCS?
  - 8b. Was the trial uncomfortable and/or painful?
9. Tell me about your experiences of SCS? (3<sup>rd</sup> interview)
  - 9a. Did you notice any variability of the sensation of SCS with movement?
  - 9b. Do you need to adjust your stimulator when you move/change position?
  - 9c. Do you find this continuous need to adjust your device difficult or cumbersome?
10. Roughly how often did you use the device (e.g. hours per day)?
  - 10a. What factors prompt you to turn the device on/off?
  - 10b. How easy or difficult did you find the recharging process?

#### Failed Trial\* Questions

4c. Do you think your expectations of SCS were met? (3<sup>rd</sup> interview)

- In the entire process?
- How did not getting one make you feel?

4d. What are your expectations for SCS in the longer term? (3<sup>rd</sup> interview)

- If it was offered again would you try it again? Do you think it might still be an option for the future?

6. Do you feel there is any information you would have liked to receive but did not?

- Following the decision not to go ahead with SCS have you received any information about what would be an appropriate next step for you?
- Would you have liked some direction on this?

7. Is there anything additional you would like to say before we finish?

*\*The term failed trial can be operationally defined as a trial which was deemed clinically unsuccessful and thus full implantation did not subsequently occur.*



**Table 2:** Participant characteristics

Participant	Age (yrs)	Gender	Pain Duration (yrs)	Pain Levels		
				T1	T2	T3
1 (001)	42	M	16	4	2.5	1
2 (002)	52	M	10	2.5	6.5	6
3 (003)	49	F	12	6	5	2
4 (004)	57	F	16	8	9	4.5
5 (007)	80	M	26	8	1.5	1
6 (008)	64	M	5	8	4	7
7 (009)*	72	M	7	8.5	9.5	9.5
8 (010)	74	F	3	5.5	7.5	8
9 (011)	69	M	16	8	2	3
10 (013)	38	F	16	5	5	5.5
11 (014)	55	M	8	4.5	0	0
12 (015)	45	M	1	7	2	8

*Table legend: M = Male, F = Female; T1 = Time 1, prior to trial; T2 = Time 2, post trial; T3 = Time 3, 2-3 months post implant (or post trial if failed trial).*

*\* Previously failed Dorsal Root Ganglion stimulation trial.*

**Table 3:** Key information needs identified by participants.

- What to expect throughout trial/SCS treatment; before, during and after (practically throughout procedure and for outcome/recovery)
- What is 'normal' regarding daily activities after procedure(s)
- Risks and adverse effects outlined specifically
- Internal/mechanical workings of the trial/SCS device (internal connectors, lifespan, maintenance, everyday use) and how it works
- What happens if SCS does not work or participants do not go ahead with the implant (including how to remove the trial device)
- Which bodily locations SCS will work for
- Notified about the tingling that will occur as part of the stimulator or possible internal feelings/sensations of the device
- Practical aspects of the wound (after trial), such as wearing a lot of bandages, possibility of bleeding or oozing
- How to carry trial paraphernalia and/or best options for this
- How to deal with aspects of comfort and personal care; best ways to manage this
- Placement of battery and how this may impact what patients wear after the device has been implanted
- Guidelines on activities when on the trial and SCS (and timelines associated with any activity restriction) (A 'Do's and don'ts' guide throughout treatment)
- Consistent message about likely outcomes or success rates (percentages of pain relief) across patients

- Different medium of instructions post care to family or carers – patients may often be unable to retain oral information, e.g. due to the amount of medication they are receiving, so family members can take this information with them in addition to what the participant receives
- A ‘Six easy steps’ guide to get started using the device
- Specific details on how often and for how long devices should be used (potentially specific to the individual)
- Which devices may be available to the individual
- Sessions on why you get pain
- Information days/sessions about the SCS procedure and treatment
- Signposts to other relevant, appropriate, and credible information
- Help to manage any developing anxieties or worries over treatment
- Expert patient/peer support contact
- How work (employment) will be impacted by SCS treatment and what the patient can do to manage this
- Practical information such as how to go about daily activities (i.e. use of a grabber to pick things up, placing things in an accessible place, using lots of pillows for comfort)
- Develop an app (mobile application) for users – detailing how to use the device, what to do/not to do whilst on trial/beginning of SCS
- A Frequently Asked Questions sheet and/or a telephone helpline