




To Trial or Not to Trial Before Spinal Cord Stimulation for Chronic Neuropathic Pain: The Patients' View From the TRIAL-STIM Randomized Controlled Trial

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ABSTRACT

Objectives: Spinal cord stimulation (SCS) is an established treatment of chronic neuropathic pain. Although a temporary SCS screening trial is widely used to determine suitability for a permanent implant, its evidence base is limited. The recent TRIAL-STIM study (a randomized controlled trial at three centers in the United Kingdom) found no evidence that an SCS screening trial strategy provides superior patient outcomes as compared with a no trial approach. As part of the TRIAL-STIM study, we undertook a nested qualitative study to ascertain patients' preferences in relation to undergoing a screening trial or not.

Materials and Methods: We interviewed 31 patients sampled from all three centers and both study arms (screening trial/no trial) prior to SCS implantation, and 23 of these patients again following implantation (eight patients were lost to follow-up). Interviews were undertaken by telephone and audio-recorded, then transcripts were subject to thematic analysis. In addition, participants were asked to state their overall preference for a one-stage (no screening trial) versus two-stage (screening trial) implant procedure on a five-point Likert scale, before and after implantation.

Results: Emergent themes favoured the option for a one-stage SCS procedure. Themes identified include: saving time (off work, in hospital, attending appointments), avoiding the worry about having "loose wires" in the two-stage procedure, having only one period of recovery, and saving NHS resources. Participants' rated preferences show similar support for a one-stage procedure without a screening trial.

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Conclusions: Our findings indicate an overwhelming preference among participants for a one-stage SCS procedure both before and after the implant, regardless of which procedure they had undergone. The qualitative study findings further support the TRIAL-STIM RCT results.

Keywords: Neuropathic pain, patient choice, screening trial, spinal cord stimulation, thematic analysis

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INTRODUCTION

Neuropathic pain is a complex and disabling condition that affects up to 8% of the adult population (1) with substantial impact on health-related quality-of-life (HRQoL) (2,3). Up to 50% of patients with neuropathic pain fail to obtain pain relief from analgesic medication (4).

Spinal cord stimulation (SCS) is an effective treatment for severe neuropathic pain (5). In Europe, North America, and many other countries, patients are required by clinical guidance to undergo a successful SCS screening trial to be able to receive the more expensive SCS implant (6,7). An expert panel defined a successful trial as the patient reporting $\geq 50\%$ pain relief with stable or reduced pain medication (7).

Screening trials give patients a short flavor of living with SCS therapy. They also allow patients and physicians a baseline evaluation of the pain relief experienced and electrical current consumption required from the device, which may impact the choice of pulse generator implanted (8). However, screening trials require duplication of procedures, thereby consuming more healthcare resources in operating room time and a second admission (9). Moreover, prolonged home SCS screening trials expose patients to a higher risk of infection (10).

Published studies to date have questioned the prognostic value of screening trials (11). While screening trials allow patients to experience at first hand the effects of SCS therapy before deciding to receive a permanent implant, they are costly, necessitate procedure duplication, are associated with an increased risk of infection and may not appropriately represent therapeutic long-term outcomes. The recommendation that all candidates for SCS should undergo a screening trial prior to permanent SCS implantation is largely based on expert opinion rather than firm evidence.

MATERIALS AND METHODS

This embedded qualitative study set out to assess the preferences and experiences of patients within the TRIAL-STIM study randomized controlled trial (ISRCTN, ISRCTN60778781). The protocol for the TRIAL-STIM study (12) and diagnostic performance, effectiveness, and cost effectiveness findings were published elsewhere (13). The following study methods are presented in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) framework (14).

Inclusion Criteria

Participants were approached from all three TRIAL-STIM study sites, after they had been found eligible to take part in the main study. The principle inclusion criteria were: aged 18 years or over; clinically a candidate for SCS as per NICE TA159 guidance; and having persistent neuropathic pain for more than six months despite conventional medical and surgical management, of an intensity of at least five on a numerical rating scale (scores 0–10). Participants were randomized 1:1 either to receive a screening trial of SCS followed by full implant in a two-stage procedure or to proceed directly to an SCS implant in a one-stage procedure.

A purposive sampling strategy was utilized with a view to including two groups of participants:

1. those undergoing a two-stage procedure (a trial period followed by implantation—usual care) TG; and
2. those undergoing a one-stage procedure (implantation only—intervention) NTG.

Recruitment

Participants were invited to take part in the qualitative study as a separate and optional element of the main clinical trial, with an additional section on the consent form indicating their agreement to take part in an audio-recorded telephone interview. If they consented to this, their contact details were passed to the qualitative research team. Randomization between the two arms for the main study was carried out at this stage, and the outcome notified to the qualitative research team to enable balanced recruitment across study arms for interviews. Participants were informed of their randomization at their study site only after the initial interview was complete, in order that their views at the outset were unaffected by the arm of the study they were to follow. Participants were initially contacted by telephone for interview, in the order of recruitment to ascertain whether they were still happy to take part. If they agreed, the interview was carried out either immediately or an alternative time to call back was arranged.

Data Collection

Interviews were conducted by one of two researchers, R.C. and R.M. R.C. is a Clinical Psychologist with experience of undertaking psychological assessment of patients being considered for SCS. R.M. is an experienced qualitative researcher at Teesside

University with no previous experience of this field. Neither of them had prior knowledge of any of the participants.

Interviews were conducted by telephone with each participant at a time that was convenient to them. Two interviews were carried out with each participant—one shortly before their planned surgery date and a second at least four weeks after the implantation of the device (four weeks after surgery for one-stage procedure and four weeks after second surgery for two-stage procedure).

A semi-structured interview guide was used to provide a framework for interviews, to ensure that consistent data were captured between participants and by each researcher while also allowing the flexibility to explore issues raised by participants. At the start of the study, a small number of participants had been recruited and were awaiting implantation before a recording device became available. To avoid their implantation being delayed, nine interviews were conducted with contemporaneous notes which were subsequently transcribed for analysis. All remaining interviews were audio-recorded and transcribed verbatim for analysis. Interviews lasted between 10 and 40 min.

Participant Rated Preferences

In addition to undertaking telephone interviews, participants were asked in conclusion to express their overall preference for a one-stage (1#) or two-stage (2#) procedure on a 5-point scale:

Strongly prefer 2#/Prefer 2#/No preference/Prefer 1#/Strongly prefer 1#.

This was carried out at the end of both preimplant and post-implant interviews. At the preimplant interviews, participants were unaware of the trial arm to which they would be randomized, so their preference could not be influenced by this knowledge.

Ethical Approval and Conduct

This study received a favorable ethical opinion from the UK Health Research Authority's North East – Tyne and Wear South Research Ethics Committee (REC reference 17/NE/0056).

Sample Size

In qualitative research, sample size is determined by the ability to explore participants' experiences in-depth (15). Qualitative data analyses do not impose restrictions on overall sample size, and even small samples can yield large amounts of meaningful data (16). Data from 31 participants are included within the analysis, representing 31 interviews carried out prior to device implantation and 23 interviews carried out at least four weeks after device implantation.

Each participant consenting to be interviewed was contacted via telephone up to three times. If they were not available and had an active voicemail service, a message was left giving contact details of the research team should they wish to participate. On the third attempt, it was explained that no further calls would be made. The same three call procedure was adhered to for the follow-up interview as well. All participants contacted were willing to take part in the interviews.

It was intended to recruit ten participants from each of the three study sites, five undergoing a one-stage procedure and five undergoing a two-stage procedure with a total recruitment target of 30 participants ($n = 15$ one-stage and $n = 15$ two-stage).

Analysis

In keeping with the exploratory nature of the qualitative study, data were analyzed utilizing an inductive approach, rather than applying a priori themes to the data. Initial analysis of a sub-set of transcripts from both sets of interviews (preimplant and postimplant) was undertaken collectively between the qualitative research team to ensure that findings were credible, valid, and shared (17). NVivo 10 software was used to facilitate the management of data.

A six-stage thematic analysis strategy was employed (18,19). Stage one: familiarization was undertaken by the qualitative research team. R.M. reviewed the entire data corpus by listening to the tapes and reading the transcripts. R.C. and H.S. reviewed a proportion of the interview transcripts each (three preimplant interviews and three postimplant interviews). Stage two: initial codes were generated by the three researchers independently. Stage three: the team then met to discuss the initial codes and to develop initial themes. Stage four: R.M. applied the initial themes to the entire data corpus. Stage five: themes were reviewed and refined to ensure a good fit with the data. These final themes were reviewed by R.M., R.C., and H.S. before being defined and named. Stage six: finally, the themes and sub-themes were presented and reported by describing them using selected direct quotations from participants for illustrative purposes.

RESULTS

Thirty-one individuals across all three trial sites participated in the initial preimplant interviews, representing 16 participants due to undergo a one-stage procedure and 15 due to undergo a two-stage procedure (Table 1). Eight participants were lost to follow-up, four who underwent a one-stage procedure and four who underwent a two-stage procedure.

The following findings are separated into two main sections. First, findings of the initial preimplant interviews are presented, where participants discussed their preferences for either a one-stage or two-stage procedure. Second, findings from the post-implant interviews are presented, where participants discussed their reflections on their experiences of undergoing the procedure.

Findings From the Preimplant Interviews

Two main themes arose from the initial interviews: expectations of SCS and preferences for a one-stage or two-stage procedure. The second theme included a number of subthemes, all reflecting reservations about the two-stage procedure: the prospect of having "loose wires," the additional time and support requirements, and the need to save National Health Service (NHS) resources.

Expectations of SCS

Participants discussed their hopes that SCS would improve their quality of life in general terms. Their current experience of persistent pain had widespread impact on many daily activities. Many participants noted that their pain interfered with their sleep, leaving them exhausted both mentally and physically; their social lives; and their ability to maintain paid employment.

It restricts everything, what you can do. I can't walk as far as I used to. You know, I'll get pain when I'm travelling, that kind of thing. So it's just generally restrictive. You can't sleep, I'm woken up in the night. (010)

Table 1. Number of Participants by Trial Site and Study Arm.

	One stage		Two stage		Total
	Preimplant	Postimplant	Preimplant	Postimplant	
Site 1	5	4	6	5	20
Site 2	5	4	5	3	17
Site 3	6	4	4	3	17
Total	16	12	15	11	54

Another participant added:

I'm not getting much sleep.... it's affecting my life full stop. I can't work and its affecting my... social life. I don't go anywhere really. (019)

For participants who were in intimate relationships, their persistent pain had affected their interactions with their partners. For some the persistent nature of the pain had caused them to become irritable and lash out at those closest to them.

And my partner is here, so I can say, I'd better say I get very grumpy with it! [the pain]. She's nodding her head vigorously. (010)

These far-reaching implications of living with persistent pain led participants to explore what their expectations were, in terms of the changes they hoped SCS would achieve. All participants expected that the implantation of SCS, regardless whether a one-stage or two-stage procedure, would reduce the level of pain they experienced to manageable levels, and allow them to take part in everyday activities once more. None of the participants in our sample discussed the removal of pain completely:

Well, it's pain reduction. It will therefore allow you to do, you know to lead a more normal life. It's not getting rid of the problem, so you've still got to be careful. You know it's not a matter of suddenly.... not doing a lot of walking, and suddenly deciding to go yomping in the Scottish Highlands, I don't think you can achieve that! So, you have to be mindful that it's taking away the pain but not the problem. (010)

Another participant added:

I'm hoping that.... every day there's something now. Every day I'm, you know, I've got some pain or discomfort or something. And I'm just hoping that, even if we're talking about it in terms of pain, I'm hoping that at least half the week is fine and allows me to do more. (049)

Preferences for One-Stage or Two-Stage Procedure

When participants were asked to explore their preferences for either a one-stage or two-stage procedure they stated overwhelmingly a preference for a one-stage procedure. It was unclear to many if or why an individual would opt for a two-stage procedure if a single stage was an option. One participant noted:

You know, I can't [understand why] there's any reason why people wouldn't want a 1-stage rather than a 2-stage. (038)

Another participant expanded:

No. Really, no, I can't see [advantages to 2-stage]. I mean I'm an engineer. I work on process development, work on production systems. There's no benefit to opening somebody up. Putting a system in, trying it, and then saying do you want it or not? And then redoing it all again. You might as well put it in, does it work? Yes? If it does – off you go. Happy days! If it doesn't – take it out anyway. (027)

Nonetheless participants were invited to consider both the benefits and disadvantages of undergoing either a one-stage or two-stage procedure more fully.

Loose Wires. The practicalities of having a two-stage procedure, especially living for a week with wires hanging externally to the body, gave cause for concern. Many participants were fearful that they, or someone else, would accidentally dislodge the wires and ultimately invalidate the trial period:

My main concern is that I do something to mess it up, with regards to the trial, I'm worried I would move the wire. (011)

From the positive point of view having a 1-stage would mean you have nothing hanging outside of the body and having to wear it on a sort of strap arrangement for a week. (038)

I think it's the fact that.... it's sort of on the outside of your body and it's more..... you've got to be probably more careful that you might snag the leads (061).

In addition to fears about moving or knocking the external leads, some participants raised concerns about the distance needed to travel back to the hospital to receive medical attention:

So if anything happens, you know, with the wires and things like that it's a long distance going back...what if they come out? What if the.... you know, what if anything happened with them? (067)

Time Needed (Two-Stage). Taking time out of daily life to attend two episodes of surgery was raised as a concern repeatedly by participants. Time taken off work was a worry for some. When presented with the choice of one or two surgical procedures, taking time off work to attend the appointments and for the subsequent recovery, having a single-stage procedure was the more attractive option:

For me it's about the time off work – being self-employed. Because you're having to go through two procedures, two times off work, everything else. And with my work being kind of seasonal, and dependent on weather, when we get good weather I don't want to be laid up. (037)

Many participants lived long distances from the hospital sites that they would need to attend. Traveling to and from presurgical

appointments, then again for two surgical appointments was daunting for them:

The other reason, which is purely selfish, is that I live a good few miles away from where the hospital is. It's quite a drive. And as I've said before driving is not the best. (038)

This was not only due to distance but because participants would have to rely on the good will of friends and family to drive them to and from these appointments. Participants did not want to put undue burden on those people:

It's such a, it's a long way to go, and I've got to, you know if I go in on the first time I've got to get somebody to take me in. then I've got to get somebody to take me back. Then the second time, I've got to get somebody to take me in, and the second time to take me back again. (018)

Support Needed. For some, the main worry was about imposing a burden on others by having to ask for their support, not only with attending for appointments and treatment but also during the period of recovery. As one participant noted:

The extra pressure that it then puts on the family as well. Because my husband's got to take a day off work to take me down there and bring me back, and the kids and, you know I just think for me I'd rather have it all done in one day. (043)

Similarly, participants who had children raised the issue of childcare while they were undergoing surgery. These participants for very practical reasons stated that they would prefer to have a single stage procedure so that they did not have to access childcare for two episodes of surgery and the subsequent recovery:

I don't want to have to mess about going to [names hospital] because I live in [names home town]. So I've got to travel over there to get these procedures done. I'm a single dad, so you know, it's not easy for me to get a babysitter for like two occasions you know. (015)

Saving NHS Resources. Many participants discussed the positive impacts a one-stage procedure would have on the NHS rather than them personally. There was acknowledgement that if a one-stage procedure was the norm, more people could benefit from SCS as it would be possible to implant more as each procedure would take less time. One participant explained:

It would be saving costs and time, you know, for the doctors. For other people that's needing the same thing as me....because I know it's not just me that has this problem. (032)

There would only be the need for one theater slot per patient, as this participant stated:

You know there's only one theatre time, there's one surgery time, there's one risk of infection. Do you know what I mean? You can increase the amount you're doing because you're only needing one theatre slot. (081)

Another participant expanded on this by noting that for a one-stage procedure there would be less input from the wider surgical team, therefore saving money for the NHS:

If it [the device] has to go in twice, then it's twice they've got the surgeon there, the anaesthetist twice, you know what I mean? It's money after money, isn't it? (018)

Other Perspectives? While all participants had stated that they would prefer a single-stage procedure and many noted the perceived benefits of it, each participant was asked whether they could see any advantages to having a two-stage procedure over a one-stage. Ease of removal of wires as opposed to the removal of an implanted battery pack was the main advantage identified. One participant explained:

They can just take the wires out, that's it, it's not for you and they don't go any further. Whereas if you have it implanted in the one go and it's not for you, it's gonna be trickier and potentially a longer process to then have it removed. (081)

Another participant commented:

Well I suppose the benefit would be that you would kind of like know it works for you. And you've kind of like, you've had a sort of slightly smaller thing done to you in a way (053).

Findings From the Postimplant Interviews

The themes emerging from the second round of interviews were more highly differentiated, reflecting the direct experience of the procedure rather than anticipation. These included: the main outcomes of treatment (largely in line with expectations); practical living with the SCS device; strange sensations/discomfort; the value of information; the importance of consistent after-care; the need to manage expectations; and further reflections on the options of one-stage or two-stage procedures.

Main Outcomes

Pain Relief. The vast majority of participants reported that their pain had been reduced since SCS implantation and for some the relief had been revolutionary. As one participant explained:

It's given me back my life again. I wish I'd had it done four years ago, never gone through all the surgery, treatment. I was a bit sceptical at first, but when they switched it on... [participant gasped]. (008)

Another participant commented:

It's marvellous...well I don't get sciatic pain anymore... which is what I was trying to get rid of. (038)

While the relief was, in most cases, apparent very quickly post-surgery many participants noted that they were reminded of the positive effects each time they either forgot to charge the battery, or did not switch the device on for some reason. One participant said:

You know it's great to get rid of the pain, and to be honest...if I forget to switch it on, or switch it off accidentally or I decide to reduce it down too much, I can soon get that pain back. (038)

Only a few participants felt that the SCS implant had not been effective in reducing their pain. One said:

Well the operation etcetera went fine. But it hasn't made much difference to the pain. (016)

Medication Reduced. A reduced level of pain was not the only positive effect of SCS implantation experienced. Participants also noted a reduction in the number and dose of pain medications taken. One said:

I've reduced my drugs by half... So I'm not suffering the side effects from the pregabalin as much. (037)

Another stated:

I was on pregabalin for...the sciatic pain. Tramadol, of course. And I was also taking paracetamol...and ibuprofen....To be honest I was on a cocktail of all those on a daily basis. And immediately I've been able to more or less drop completely paracetamol and ibuprofen. (Now) I'm generally more alert and more awake.... (038)

Improved Function—Able to Sit Longer, Walk Further. Many participants experienced benefits of improved function—the ability to sit for longer periods of time, walking further, enjoying activities with friends and family, or doing housework. One participant commented:

I can sit a little bit longer in the car...I can drive a little bit, well quite a bit further now...I'm also getting out with the dogs now as well. (019)

Another said:

It's been amazing to actually have a life...Even just sweeping the floor...Making food, you know, EVERYTHING! (067)

Other comments included:

I'm standing more, sitting more, walking more. (081)
On a day to day basis I can now say, right we're gonna do stuff. We're gonna go places... you know I'll play with the grandchildren, I can do stuff, and be part of the family. Which I wasn't being for the last few years particularly, I've been pretty much laid up. (038)

Made a huge difference to sleep - able to sleep much longer than before. Fantastic. (004)

Observations of Change by Family Members. For several participants, improvements were not only experienced by themselves but also by their friends and family. As this participant explained:

Because I must admit when you're in pain for such a long time you can become a miserable git. And I think it's just frustration, just because the pain's so...it just drives you nuts. Even me wife said, you're a lot happier these days. You seem a lot happier. You're not as...fed up with everything. (037)

Another commented:

Well I'm...not able to do more as such. But.. I can go out and sit for lunch. Take for example Friday, I went out for lunch with my Mum. Before I'd be sitting there in agony. And I wouldn't really say a lot. And my niece noticed that I was a lot more bouncy and happier and, and not writhing in pain..... A huge difference.. (087)

Practical Living With SCS

One new theme emerged as a consequence of practical experience of day to day life with an implanted device. Two main areas were highlighted: the ability (or otherwise) to change the settings of the device to relieve pain; and participants' experiences of charging the device.

Ability to Change Settings. Some participants in the study had the facility to change the settings of their own device and cycle through the programmes to find those which gave most relief. Others had to have the settings changed by a health professional at a hospital appointment. Participants noted that the relief from each setting was not necessarily long-lived and that "cycling" through different settings offered them the opportunity to experience continued relief. As one participant described:

I've been messing about with power settings. But since I've found settings that I've liked, I'll stick on a setting for about a week, ten days. And then I'll change it to another one. Because you seem to get used to it...and then I change to another one and it seems alright then swap back...that seems to control the pain... (037)

Other participants commented:

I'm changing the programme every three days, keeping a diary and going back for review... So far, I've found three programmes that I'm comfortable with. (008)
I've got a couple of settings that I've got preference on. And I sort of just alternate every other day, between the two. (019)
I barely notice it now [pain]. I do notice it if I have to turn it up, as I said. And a couple of times I've got to a point where I've had to turn it up, but it physically stops me from walking... (032)

Participants who were unable to change their settings themselves felt frustrated that they had to wait to go back to the clinic to have the setting changed and experience pain relief. As one participant below noted:

I've had the 'ump today because I've not been able to change me setting. I'm back in [clinic] again tomorrow. (067)

Charging the Device. Participants also discussed their experiences of charging the device. One noted feeling better when the device was fully charged:

Sometimes I feel more wiped out than normal, when the battery's running down. I feel better when it's fully charged. (008)

Regular charging of the device is necessary to ensure pain relief:

If I don't keep it plugged in the battery turns off. You can feel a difference then. (016)

However, most participants explained that the process of charging had a relatively low impact on their lives, and for some it offered an opportunity for "me time." As one participant noted:

It's no trouble at all. I'm catching up with the touring car racing that was on yesterday on the tele'...So I'm watching a couple of those races while I'm just charging me battery up. So that needs doing every three or four days...It takes an hour and half, two hours maybe. And I can move around while it's doing it. But you know I'm quite happy to sit and watch a programme while it's happening. (038)

Sensations and Discomfort

Strange Sensations. Some participants described experiencing strange sensations which they had not expected since having a device implanted. Some reported electric feelings through their body:

From the waist down, you know I could feel it, everything firing. Like electrodes. I could feel them all firing from all over the lower half of me body. It was [strange] to start with. And I've got used to it now. (032)

Another added:

I'm quite happy putting up with the [sensations], at the moment I've got the sort of tingling electrical shock up my legs and everything. And that me tells me that it's working... I'm quite happy to feel that...You know I'd much rather have that than pain. (038)

Battery/Lead Positions. The positioning of the battery pack underneath the skin and the wound site had the potential to cause new acute pain for participants. As one participant noted:

The only other problem that I'm having is that around the anchor sites for the leads, the doctor explained that they'd been stitched in over a little tube...I'm getting quite a lot of pains from that. Particularly when I'm driving... (026)

Others were aware of pain and attributed it to different aspects of having a foreign object in their body. As one participant explained:

But sometimes that area hurts where it is, and where the two wires go into your spinal cord. That's painful as well every now and again. (016)

Some participants felt that the battery moved around a little in the cavity:

I think the only problem, the main problem is obviously once you've been sat for a while it sort of pushes it up if you know what I mean. And probably causes us, why then I get the pain. (067)

While others experienced pain when applying pressure to the site:

The only thing I still struggle with is lying flat on my back... and sitting in a hard back chair. Anything that puts direct pressure onto the battery. (081)

Value of Information

It was clear from the interviews that participants valued having as much knowledge or information as possible—whether from other patients, or through their own research. They also thought highly of clinical staff being willing to communicate with them openly.

From Other Patients. Some participants had the opportunity to speak to other people who had undergone the procedure prior to their own treatment. The opportunity to ask questions and receive honest answers and advice from those with experience was seen as very helpful. One of the trial sites offered this opportunity in the form of a support group for prospective and former patients to provide a forum for advice. One participant discussed this:

I thought that was an absolutely fantastic idea...It is really, really good that patients can actually meet patients that have had it done. And see real people with it, and ask proper questions. Because if somebody asked me does it hurt when you have it fitted, I'll just tell them, yeah it does. It's bloody awful for about two or three weeks. It's awful, but you get used to it. (037)

Other participants had sought support through online forums, which acted as a network to compare experiences:

I met another lady on a forum who I talk quite a lot with. And she had it done the other way [two-stage procedure]. And her journey just seems so much longer than mine. She was all taped up and stuff in all that heat. So she was really

uncomfortable, and sweating and reacting to the tape. And had all these extra issues that I didn't have by having it done in one go. (081)

Internet Research. Participants utilized the internet not only for support from others who were having similar experiences but also to gain knowledge about what to expect. However, researching the Internet did not always uncover success stories to provide reassurance:

[I] knew what to expect. I didn't search for information too early, till I knew it was going ahead. I'm aware that online you see the bad - horror stories - more than the good. (004)

Another participant added:

I actually had a few thoughts of ... what if it doesn't work? Because a lot of people say that once you've had the trial that works, but if it works for you then normally the permanent implant doesn't work. You know when you've read all different stories? And I was a bit apprehensive. But straight away it worked for me. (067)

Importance of Consistent Aftercare

All participants were happy with the aftercare they had received from the trial site teams. One participant explained:

They bend over backwards and they're very helpful going through it all. And you know I'm very happy with what they've done. (019)

However, some participants, who lived some distance from the trial sites, explained that accessing aftercare could be troublesome, especially if out of hours. If advice was needed in relation to SCS, participants were likely to seek support from healthcare services local to them. As one participant stated:

I did have a concern at one point, me scar was very purple. And well it was very pink at one bit, and very purple in another bit. But I sought advice at the hospital here at [local hospital] just to be on the safe side, it wasn't like a wound infection. I know they'd told us to go to the [trial site] if there were any problems. But it was a weekend and obviously there's nobody in Pain Management at the weekend. So I just popped up there, and the Nurse Practitioner had a look and said, no it looks fine. (019)

Need to Manage Expectations

In the initial interviews, many participants had acknowledged that having an SCS implanted was not a guarantee that their pain would be removed completely. Many were realistic in their expectations, hoping simply for significant pain reduction. However, several participants noted in their follow-up interviews that SCS was not living up to their hopes. One participant discussed the positive and negative effects of SCS:

It's definitely [made a difference] - the stimulation hasn't been able to reach my foot, the main problem - but the knee to the ankle is not as severe, [there are] fewer cramps and spasms. I've had none at all since the permanent implant - I was having them every night. (004)

Another said:

Overall it's, I'm not disappointed. Well I am and I aren't. It's better than nothing. It's doing a bit of good which I'm grateful for. (016)

A few participants felt that the SCS was not working for them at all. One described their disappointment:

Absolutely devastated that it didn't work. Never expected for a moment that it wouldn't. I was waiting for it every day. (003)

Another stated:

No, well apparently it only works for about eighty percent of the people it's put in. I must be one of the twenty percent-ers. (016)

Preferences: One Stage vs. Two Stage

As in the initial interviews, the vast majority of participants still felt that having a single stage procedure was preferable. The sub-themes clustered around practical differences between the two options, similar to those anticipated at the outset: the benefits of having everything done at once, including a single period of recovery; and the awkwardness of having "loose wires." However, there was one additional concern: recognition that the surgical procedures were more serious and required more healing than expected.

Benefits of Having It All Done at Once. Participants who had undergone the one-stage procedure were generally happy about it, for all the reasons outlined above. One participant discussed how having a single procedure prepared you mentally for success:

You know, it was a real big difference from that point of view. And I just think psychologically you go in once; do you know what I mean? And if you're having the trial there's an element of failure of that to me. Because you're going to trial something that may work, or might not work (081)

Others were happy to have just one period of recovery:

I think it's always better just to have one operation really. (026)

And to have just one hospital admission:

Just the one admission to hospital, do you know what I mean? Just the one procedure. And obviously...it's kind of

Table 2. Treatment Preferences of Participants on a 5-Point Scale, From Strongly Prefer Two-Stage SCS to Strongly Prefer One-Stage SCS Preimplant and Postimplant.

	Pre-SCS implant	Post-SCS implant
Strongly prefer two-stage procedure	N=0	N=0
Prefer two-stage procedure	N=1*	N=1
No preference	N=1	N=1
Prefer one-stage procedure	N=3	N=0
Strongly prefer one-stage procedure	N=10 ⁺	N=9
	N=16 [‡]	N=12
Total	N=31	N=23

■ Randomized to one-stage procedure * Lost to follow-up N=1
■ Randomized to two-stage procedure † Lost to follow-up N=3
‡ Lost to follow-up N=4

infections and all stuff like that from a medical point of view. But just me only having to go in once. (081)

On the other hand, participants who had undergone the two-stage procedure discussed the added costs in terms of time and finances to attend two appointments—for the trial and the permanent implantation.

You know, just simply from the fact that it's a day procedure, but I had to be nearby the hospital to have it checked. We had to book accommodation nearby...there's double the costs for a start...And that's, you know, that would not be needed if it was a one stage procedure. (038)

Loose Wires. Participants who had undergone the two-stage procedure discussed and confirmed similar concerns to those raised in the preimplant interviews. Many found having wires external to the body for a prolonged trial period quite uncomfortable and feared they might dislodge them. One participant explained:

I was [scared of] catching it on things. Like just coming from the bathroom. I was coming, I can't remember if it was the bathroom door or the bedroom door. I'd stopped to do something and turned. And of course the handle got among the wires, and luckily my wife spotted it. Otherwise I would have pulled them! But just like for, wearing clothes and that as well. That was sort of bulky. (019)

Another explained:

So I had to walk around with wires dangling out me back into the remote unit on me belt...it was a bit awkward, you know, my whole back with covered with plaster. So it was a bit itchy and a bit uncomfortable. But it was alright. I think if, you know if I'd been given a choice, I'd have probably opted to have it done all in one go (038)

Aside from concerns about dangling wires, one participant worried about the risk of infection between the two procedures:

I don't know but you can imagine there's more of a chance of infection doing it that way as well. Opening a wound... with the two-stage procedure. Because you're leaving the hospital with actual wires hanging out of you. (038)

This Is Serious Surgery. In the preimplant interviews there was little consideration of the extent and potential impact of the surgery. However, at follow-up several participants considered that they had undergone major surgery—something they had not quite understood previously. One participant stated:

I had it put in in two stages - then another operation to have it taken out. I didn't realise they were such big operations. (003)

Another participant said:

Whatever they tell you, they're not minimal procedures. They're quite, you know quite painful, and they're quite uncomfortable. And, you know, it takes a little while to heal afterwards. But the results really seem to make it absolutely worthwhile. (038)

Other Perspectives. Despite the overwhelming support for a one-stage procedure, one participant who had undergone this and not experienced any benefit discussed their ambivalence about which procedure would have been preferable:

I suppose I've had the disadvantage of not seeing how well it works before going for the full operation. And given the fact that it doesn't seem to have worked that well in me, I don't know whether maybe that would have meant that I would have not had the full procedure? And, therefore, that I might not have gone through so much. (026)

Another stated:

I would have hated to have, hated, hated, hated to have had it put in and have been no better off. To have gone through that... (O19)

Participant Rated Preferences

At the end of both preimplant and postimplant interviews, participants were asked to express their overall preference for a one-stage or two-stage procedure on a 5-point scale:

Strongly prefer 2-stage/Prefer 2-stage/No preference/Prefer 1-stage/Strongly prefer 1-stage.

Their responses are given in Table 2. The arrows indicate the relationship between preimplant and postimplant preferences for each individual. It is of note that 26 of 31 participants expressed a strong preference for a one-stage procedure preimplant (16 randomized to one-stage and 10 to two-stage). Of these 26, 17 participants were of the same opinion postimplant (12 having undergone one-stage and 5 having undergone two-stage). Seven were lost to follow-up. In addition, three participants expressed a preference for one-stage at preimplant interview, increasing to a strong preference for one-stage at postimplant (all having undergone two-stage).

Only one participant expressed a preference for two-stage at preimplant interview (and was then lost to follow up). And only two participants changed their opinion away from one-stage.

DISCUSSION

The findings indicate an overwhelming preference among participants for a one-stage SCS procedure both before and after the implant, regardless of which procedure they had undergone.

Themes emerging from the interviews about the reasons for this preference are broadly similar between preimplant and postimplant time points. Both before and after, themes favoring the choice of the 1-stage option include: saving time (off work, in hospital, attending appointments); avoiding the worry about having "loose wires" and the impact this may have in the two-stage procedure—in other words, an external wire which could snag on something, or become dislodged; and saving NHS resources (doctors' and other staff's time, medical devices and materials). In addition, a theme from the postimplant interviews reflects the advantage of having only one surgical intervention, and one period of recovery. There is a sense that some participants had not fully grasped the extent of the intervention, or the separate acute pain and length of healing involved.

Of those participants who changed their opinion following the implant (six in total), only two moved away from a preference for a one-stage procedure (see Table 2). Both these participants originally expressed a strong preference for a one-stage procedure but were then randomized to a two-stage procedure. One of these changed to a mild preference for two-stage, commenting: "I've changed my mind a little - it's better to try it. It's a lot to go through if it doesn't work." The other was deemed on balance to have changed to a neutral response, commenting: "I still like one procedure to be honest. Not being able to shower [with 2-stage] ... I'm 50-50 really."

In addition to these novel findings, a number of general themes emerged from the interviews which are in line with previous studies.

First, the value of knowledge and information for SCS patients from a variety of sources was strongly emphasized (contact with other patients, selective internet searching, advice from staff). Similar conclusions are reached by earlier qualitative studies including Sparkes et al. (20) highlighting the value of access to expert patients; Gjesdal et al. (21) pointing out the important role of the nurse; and Ryan et al. (22) incorporating a list of practical information needs for SCS patients. There is clear agreement that reliable information is of crucial value, enabling people to form their own opinions and develop a framework to support their own decision-making.

Second, SCS is neither a complete cure for pain nor is it a standalone treatment. There is a continuing need for the individual to engage with coping strategies, and preferably to receive preparation for this beforehand. There is likely to be ongoing discomfort, as well as unusual sensations. Also depending on the type of device implanted, the individual may need to adapt to a regular routine of re-charging the battery. For all these reasons, there is a need for personal adjustment to a different way of life, involving effort to manage expectations of the treatment. Again, similar points have been made by previous studies. Henssen et al. (23) refer to the constraints and possible disadvantages of SCS. Gjesdal et al. (21) draw attention to the challenges in adaptation to everyday life with SCS; and Turner (24) suggests that psychological intervention in conjunction with SCS may support the process of adjustment, and improve outcomes. A recent systematic review of qualitative research into patients' experiences of neuromodulation concludes that adjuvant psychological therapy should form part of an overall pain management plan, including provision for ongoing emotional and psychosocial support (25).

Third, in relation to the procedure itself (implantation of the device, with or without a trial), the severe acute pain and length of physical recovery had a significant impact for many participants, and this was a factor contributing to their preference for a one-stage procedure. Participants were more inclined to want only to go through the procedure once. Sparkes et al. (20) have previously acknowledged the discomfort associated with the treatment, which may come as a shock without adequate preparation beforehand.

Finally—and despite the limitations of SCS—the themes indicate that treatment outcomes are broadly in line with prior expectations. Preimplant interviews suggest that expectations include pain reduction (not elimination); improved mobility; increased participation in daily activities; and improved quality of life. Postimplant interviews reveal a similar pattern of outcomes, with reduction in pain evidenced in some cases by a decrease in medication. Earlier studies have arrived at similar conclusions—Henssen et al. (23) relating to expectations; Han et al. (26) to SCS outcomes; and Ryan et al. (22) to both. The present study also has one new finding in relation to outcomes—namely that beneficial changes may be observed favorably by family members, which appears to be a powerful reinforcer. Not only is there the prospect of a reduced level of pain, with increased activity and improved quality of life; there is also the satisfaction of seeing family members appreciating these benefits and possibly sharing in reduced burden.

One additional point worthy of comment is the concern expressed by participants both preimplant and postimplant for saving NHS resources, by having a one-stage procedure. The savings were related to staff time and equipment. In the context of SCS, we believe this to be a novel finding. It is possibly due in part to the structure of interview questions in this study (with an explicit focus on advantages and disadvantages of the two procedures); and in part to the current frequency of media reports on pressures within the NHS.

Strengths and Limitations

To our knowledge, this is the first study to investigate patients' preferences about whether to undergo an SCS screening trial prior to permanent implantation. We sampled opinion across all three centres involved in the trial, and consequently our findings can be generalized to UK practice. Participants were drawn from both arms of the study, screening trial and no trial, and interviews were undertaken both before and after SCS implantation, giving the widest possible range of perspectives. The initial interviews were carried out before participants were aware of the arm to which they had been randomized, with the intention of removing potential bias due to expectations.

The study also has some limitations. It was intended that follow-up interviews should be carried out four weeks after complete SCS implantation. However, due to variations in practice among the three centres this was not always achieved, and some follow-up interviews took place up to eight weeks after implantation. In consequence, these participants had a longer recall time. Also it was not possible to re-establish contact with eight participants after implantation, and they were lost to follow-up. Furthermore the follow-up interviews conducted did not include a participant who had failed a screening trial, so it was not possible to consider this perspective.

Policy and Practice Implications

The findings of this study have potential implications for both policy and clinical practice:

- From the patient perspective, there is a clear preference for a single-stage SCS implantation procedure without a preimplant trial period. In conjunction with the quantitative results from the trial, this is relevant to consideration of the future policy framework for SCS.
- Informational needs of patients undergoing SCS remain a high priority, with a balanced approach to multiple resources including expert patients.
- Specific preparation both for the procedure itself, and also to assist adjustment to the realities of living with SCS, should form an essential aspect of patient care.
- Appropriate support to patients (including psychological intervention) should be considered throughout preparation and follow-up care, to optimize their prospects of benefitting from the treatment and having improved quality of life.

CONCLUSION

The results of this qualitative study indicate that patients who undergo SCS for the management of neuropathic pain have a strong preference for a one-stage procedure, bypassing the currently required screening trial. These findings further support the results reported by the TRIAL-STIM RCT. In addition to screening trials not providing patient benefit and not representing value for money, patients would prefer not to have a screening trial prior to implantation of the SCS device.

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Authorship Statements

Raymond Chadwick, Sam Eldabe, Jill Bell, Morag Brookes, Rui V. Duarte, Jenny Earle, Ashish Gulve, Susan Jowett, Rod S. Taylor, Simon Thomson, and Harbinder Sandhu were responsible for the original proposal, securing funding for the trial and drafting the original protocol. Sam Eldabe as chief investigator had overall responsibility for the management of the study. Raymond Chadwick, Rebekah McNaughton, and Harbinder Sandhu conducted the qualitative component of the TRIAL-STIM study. Raymond Chadwick, Rebekah McNaughton, and Harbinder Sandhu wrote the initial draft of the manuscript. All authors contributed to drafts of the manuscript and approved the final version of the manuscript.

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COMMENTS

This article is really interesting. It represents the patients' point of view, and evaluates multiple aspects of both expectations and preferences on the type of procedure to be performed (single or two stages). I think these results were predictable, considering the lower risk of infection, fewer surgeries, difficulty in reaching the hospital etc. It is also necessary to evaluate other aspects of health economics. What is the point of view of scientific societies regarding the trial? What are the reimbursement criteria for the procedures? Is the one-stage procedure really convenient, from the point of view of reimbursement, for hospitals? The possibility of offering different stimulation modalities could allow the use of the one-stage procedure in the majority of patients. This concept is certainly even more valid in the terrifying pandemic that the world is experiencing.

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This is a very interesting paper that looks at patients' preference for either a 1 or 2 stage SCS procedure. The patients' responses were interesting and revealed information that has not been discussed previously, like the patients' concern about the impact on the healthcare systems and the value of discussing the procedure with patients who had undergone the procedure prior. Finally, it was interesting that there was an overwhelming preference for a 1-stage procedure.

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