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‘Functional Electrical Stimulation (FES) impacted on important aspects of my life’ – A qualitative exploration of chronic stroke patients’ and carers’ perceptions of FES in the management of dropped foot.

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Abstract

Purpose
To explore the impact of Functional Electrical Stimulation (FES), as applied in the management of dropped foot, on patients with chronic stroke and their carers.

Method
A qualitative phenomenological study was undertaken. Participants were recruited from the Lothian FES clinic. Data were collected using semi-structured face-to-face interviews and analysed using the framework of Interpretative Phenomenological Analysis (IPA).

Results
Thirteen patients and nine carers consented to participate in the study. The overarching theme that emerged from the data was that ‘FES impacted on important aspects of my life’. Four sub-themes were identified these were: (1) ‘Walking with FES is much better’; (2) ‘FES helped regain control of life’; (3) ‘Feeling good comes with using FES’; (4) ‘FES is not perfect but it is of value’.

Conclusions
This study provides insights into the perceptions of patients and carers of the impact of FES. These results have implications for clinicians delivering an FES service for the management of dropped foot after stroke.
INTRODUCTION

In the United Kingdom stroke affects between 174 and 216 people per 100,000 of the population each year [Royal College of Physicians, 2008]. Approximately 20% of stroke patients will present with a dropped foot [Burridge, 2001]. FES is a treatment option for the management of dropped foot following stroke, although not widely available in the UK [NICE, 2009]. Application of FES produces movement in muscles paralysed due to central nervous system lesions e.g. lifting the foot during the swing phase of gait. Research has demonstrated FES can improve walking speed and muscle strength after stroke [Glanz et al, 1996; Kottink et al, 2004; Robbins et al, 2006; NICE, 2009]. A Lothian FES service, predominantly for the management of dropped foot, has been established for a number of years. In line with previous evidence [Glanz et al, 1996; Kottink et al, 2004; Robbins et al, 2006; NICE, 2009] a service evaluation on 40 stroke patients found statistically significant improvements (p<0.001) in gait velocity and cadence of 39% and 14% respectively [Shiels et al, 2008]. Anecdotal reports from both patients and carers suggested benefits beyond gait alone. There has however, been limited qualitative exploration of this modality.

Two retrospective studies by Taylor et al, 1999, and Taylor et al, 2004, used postal questionnaires to capture patient views on the use of FES for dropped foot. Both studies reported a reduction in effort of gait as the key reason for ongoing use of the device. Problems were highlighted in relation to electrode positioning and equipment reliability. Satisfaction with the FES clinical service was good [Taylor et al, 1999; Taylor et al 2004]. In both studies bias may have been introduced as the
provider of the clinical service issued the questionnaires. However, the authors acknowledged this problem and the influence that it may have had on results gained. Both questionnaires consisted primarily of closed questions and provided little opportunity for participants to freely express their perceptions of FES. It could be argued that other qualitative methods might elicit more in-depth perceptions about the use of this device in the management of dropped foot.

A qualitative study by Malone et al, 2002, explored users’ and partners’ views of FES and the meaning it held in their lives. Twelve patients of mixed pathologies, from the Salisbury FES service, and five of their partners, were interviewed and asked to tell the story of their life prior to and after receiving FES. Participants described how FES had positively changed their lives, namely: increased confidence and speed of walking; reduction of falls/tripping; increased distance walking; greater normality of walking and improved social participation. Negative comments were linked to FES set-up and cosmesis. Partners reported that they felt more confident leaving their FES user at home alone. It was concluded that FES had positively changed their lives. Similar to the Taylor et al, 1999 and Taylor et al, 2004, studies, a member of clinical staff associated with the FES service undertook this study. The author acknowledged that an independent organisation could have been used to reduce bias. The interviews were undertaken on patients with mixed pathologies and those with a diagnosis of stroke only amounted to four. It is unclear whether any of the partners were carers of persons with stroke. The majority of FES users had been using the device for a relatively short period of time (eight months). It might be
argued that the small number of interviews with patients after stroke and the short length of time using FES reduces the depth and richness of the data collected in relation to the management of dropped foot after stroke.

All three previous studies were carried out on mixed populations (stroke, multiple sclerosis, spinal cord injury, traumatic brain injury and cerebral palsy) [Taylor et al, 1999; Malone et al, 2002; Taylor et al 2004]. FES set-up and ongoing maintenance may differ in these patient groups due to varying disease processes. This may have influenced patient experiences and perceptions of using FES. As a result, the transferability of these results [Taylor et al, 1999; Malone et al, 2002; Taylor et al 2004] to a stroke population could be brought into question. Further qualitative research is therefore required exploring the impact of FES for the management of dropped foot on the lives of patients with stroke and their carers.

The aim of this study was:

- To explore the impact of FES as applied in the management of dropped foot on patients with chronic stroke and their carers.

**METHODS**

**Study Design**

A qualitative phenomenological research study was undertaken using semi-structured face-to-face interviews on 13 stroke patients and 9 carers.
**Ethics**

Lothian Research Ethics Committee granted ethical approval for this study. An introductory letter and information sheet were sent by post to potential participants. Those interested contacted the independent researcher directly. Interviews were organised at a time and venue of the participants’ choice. Written consent was obtained prior to interview. Participants could withdraw at any point and strategies were established to manage potential interviewee distress.

**Participants**

Eligible participants were stroke patients with dropped foot and carers who had attended the Lothian FES service for more than 6 months and had no severe communication difficulties. Purposive sampling with a documented stratification process was applied to encompass the views and experiences of as diverse a stroke population as possible. Participants were stratified according to the patients’ gait velocity at time of FES set-up and the number of years since stroke. It was recognised that valuable data from patients with marked communication difficulties would be lost due the method of data collection (face-to-face interviews). For that reason, the carers of patients with stroke using FES who had communication impairments were actively sought. Fifteen patients with stroke and eight carers were approached to take part in the study.
Interviews

Semi-structured interviews, using a focused interview guide, were conducted by an experienced independent researcher who had no involvement in the FES service. The interview guide (table 1) was developed from the literature and clinical experience of the research team; two academics and two specialist neurological physiotherapists. This sought to be as broad and open as possible to enable participants to freely express their views and perceptions regarding FES. Interviews were digitally recorded, anonymised and transcribed verbatim by a research assistant. Participant verification of their interview summary was undertaken.

[Insert table 1 here]

Data analysis

The framework of Interpretative Phenomenological Analysis (IPA) was applied to all transcripts [Smith, 2008]. IPA is a recognised phenomenological based approach that can be applied to qualitative research. Transcripts were read and re-read to identify recurrent ideas, thoughts and concepts and emergent themes were identified and coded. During this process themes were constantly checked and reviewed to ensure that they reflected the views of the participants. Following initial analysis of the transcripts, codes were discussed and verified by the research team. Subsequently agreed codes were applied to all transcripts and connecting themes were grouped to give overarching themes.
RESULTS

Thirteen patients and seven carers consented to participate. In addition two further carers, who had been present and contributed during patient interviews, consented to have their views included. Ten patient and six carer individual interviews and three joint patient and carer interviews were conducted. Demographic and participant characteristics at time of interview are detailed in table 2. All participants were FES stroke patients and carers from the Lothian FES service with a mean (SD) patient age of 64.37±9.48 years, time since stroke of 4.63±1.93 years and time since FES set-up of 2.37±1.01 years. The mean (SD) length of interviews was 44±14.5 minutes (range of 20-70 minutes).

[Insert table 2 here]

‘FES impacted on important aspects of my life.’

The overarching theme emerging from the wealth of rich data was ‘FES impacted on important aspects of my life.’

From this overarching theme four sub-themes were identified relating to both patients and carers

- ‘Walking with FES is much better’
- ‘FES helped regain control of life’
- ‘Feeling good comes with using FES’
- ‘FES is not perfect but it is of value’
These sub-themes are illustrated using anonymised quotes.

**Sub theme 1. ‘Walking with FES is much better’**

An emergent concept throughout the interview transcripts was the positive impact that using FES had on mobility. Patients clearly articulated their perceptions that FES directly improved both their walking ability and quality.

“The difference between using FES and not using it is something like probably 15 or 20% improvements to the walking. So clearly I was thrilled by that and I also feel that because I get a genuine real fright now the quality of my walking is much, much better. The quality is better, the stamina is definitely better and I’ve done a lot of work, you know, walking to the shop rather than taking the car, walking to post a letter rather than taking the car, to build up my stamina and strength. But that was apparent immediately, as soon as I put it on.” (Keith, patient)

“So that it looks better, it feels better and I feel I can walk better.” (Christopher, patient)

“I think my walking’s getting a bit better, you know, because it’s just natural you know” (Matthew, patient)

Perhaps unsurprisingly the emphasis for carers was slightly different. They associated the benefits of FES with a reduction in the use of walking aids and an increase in mobility as Shona and Moira described:
“I mean he wouldn’t be able to have mobility, anywhere near the mobility that he has now if he didn’t have the FES.” (Shona, carer)

“Using the stimulator, the foot stimulator he can get around in the house without a stick.” (Moira, carer)

These changes were noted immediately on application of the device as Lisa eloquently explained:

“He walked without it (FES) and then he walked with it and, you know, you could see the difference right away when he was walking down the corridor.” (Lisa, carer)

Aaron reflected on how and why he felt FES had contributed to his partner’s walking.

“I think it (FES) makes you think you’re more normal. You’ve got away from the splint idea. You can actually, on a good day when she’s walking she just walks wae (with) a wee (little) bit of a limp with her stick. She didn’t walk as well as that ever before.” (Aaron, carer)

Sub-theme 2. ‘FES helped regain control of life’

Patients and carers expressed the significant contribution of FES in returning to previous activities and roles. These direct changes also had indirect benefits for carers.

For patients such as Keith it was returning to treasured family activities that he had enjoyed prior to his stroke.
“As a family we tend to enjoy walking, like Boxing Day there’s this traditional. We traditionally walk to a hotel with a bar (approximately 1.5 Kilometres), have a pint, walk back. So it’s nice to be able to do that again. I did that this year” (Keith, patient)

Steven went further, and believed that FES allowed him to resume his role in society, facilitating his return to work and he identified this with regaining his previous lifestyle.

“But if it wasn’t truly for that (FES) I would not have the lifestyle I’ve got, definitely not.” (Steven, patient)

In some cases it was the capacity of FES to allow greater independence with activities of daily living, so negating the need for home modifications. Matthew felt that FES had increased his mobility and independence on the stairs that he no longer required a stair lift.

“I wanted a toilet down the stairs, as I said, I’ll even, I says I’ll go halfers with you. But she said oh no. So we settled for a chair lift. But I had the chair lift for a while but when I got this I started, I can walk up the stairs now.”

INTERVIEWER “OK, so because of the FES you don’t actually need to use the stair lift anymore?

“Aye (yes), I can walk up the stair.” (Matthew, patient)
Carers noted that their partner had greater mobility and this positively influenced their ability to participate and access activities in the community.

“It (FES) made a difference to that. You could say without it she would be virtually house bound in my opinion.” (Aaron, carer)

“It’s (FES) made an awfy (awful) difference. It’s given him total independence. I go out into the car and he just trots out behind me and he gets into the car on his own and he gets out of the car on his own, and he can go shopping.” (Marie, carer)

Patients were observed resuming previous roles and re-gaining independence. Carers reported a reduction in their caring responsibilities and workload. Marie commented on the return of her partner to a former chore in the home.

“I think it’s (FES) lessened my workload.

INTERVIEWER “In what way?”

“Well he now cleans windows for me and does different things. He always - very hygiene conscious my husband, always has been. The kitchen was always his domain; nobody could clean the kitchen like my husband.” (Marie, carer)

She further explained:

“So now, he’s got that job back, and he cleans the windows that he can reach, he cleans the inside of the windows for me and he helps me, cleans the bathroom.” (Marie, carer)
Even for the less physically able patient small improvements in their functional ability had a direct and marked impact on the carer and their caring role. As Daniel described:

“I just think the fact that you don’t have to be watching my wife all the time and she doesn’t have to be shouting for you all the time. If she wants to get up and walk around the room or change chairs she just does it now and I don’t worry about it so much.” (Daniel, carer)

**Sub-theme 3. ‘Feeling good comes with using FES’**

Psychological benefits from using FES were noted by both patients and carers.

Colin attempted to rationalise why FES had such a positive impact on him.

“But it (FES) made a difference. It gave me confidence, I lifted my foot, I didn’t trip, but I think it’s like anything else, is it the machine that does the good or is it the psychological aspect of it?” (Colin, patient)

For Keith it was the positive feelings that he experienced through comparing his progress and abilities with those around him.

“I get to overtake old ladies with sticks rather than be overtaken by them! But I meant that’s a way of saying I’m pleased that I’m maybe able to walk at a, I would think a pace reasonably close to normal. My father a few months, probably a couple of months ago, I think we were out walking in the park. He told me to slow down. Now OK, he’s approaching 70 but he’s still very fit and active. I mean my mates if we’re out and about will say, they’ll comment on
the fact that I’m just getting about much, much quicker than before, so, and that to me is a very, very positive thing.” (Keith, patient)

Similarly, Marie described how the improvement in her husband’s appearance had a direct influence on her own mood.

“It makes me feel good because it makes him look good,” (Marie, carer)

Daniel on the other hand had mixed emotions. Whilst he felt positive about his wife’s increased confidence and functional ability, the fact that such simple achievements elicited a wealth of emotion from him was sometimes difficult to understand and cope with.

“You know the other day I was out in the garden and next thing she was banging on the window to me. It was a shock at the time but you feel good about it. That’s the elation I find hard to cope with sometimes. That’s great because you wouldn’t think it if the person was normal, you know, if she could walk normally, and I find that difficult.” (Daniel, carer)

Improvements in confidence were noted in both groups with far reaching consequences.

“Yes, I mean it’s just more confident and my wife wasn’t hanging on to me all the time.” (Colin, patient)

“It gave him more confidence. I was more confident about not hovering over him all the time.” (Alison, carer)
**Sub-theme 4. ‘FES is not perfect but it is of value’**

Both patients and carers verbalised some issues with the application and use of FES. Despite these, the positive benefits outweighed the negatives such that all but two patients continued to use FES on a daily basis.

Some patients described difficulty with set-up and the need for support from a carer with this.

“And the basic problem with me about the FES is I can’t put it on myself, I need my wife to do that.” (David, patient)

David recognised however that he had not attempted self set-up but hypothesised why he felt it would be too difficult, stating that:

“Well I couldn’t do it. Well I suppose I could do it with a struggle. It’s hitting the right spot where you put the electrodes” (David, patient)

Despite trials and tribulations with set-up Steven persisted with FES as he valued the benefits.

“I mean OK it’s a bit of a pain in the backside all these cables and what else, but I mean it is a way of life and you have to accept that.” (Steven, patient)

Some carers expressed the problems they had finding the correct electrode position on a daily basis.
“I think everybody has a slight difference in where they put them (electrodes). But once you find a place that’s suitable for you then they work. It definitely works.” (Moira, carer)

For other carers, concerns were reported in relation to cosmesis of the equipment. Again this did not prevent regular use.

“I didn’t like the look of it very much. But I mean if it was going to help, you know, it did’nae [did not] matter what it looked like really. I mean its nothing really its just pads on his leg and wires up, kind of like a wee (little) battery thing in his pocket. But it made a difference.” (Lisa, carer)

Participants expressed concern using the equipment when travelling. This related more to heightened airport security concerns and the possible perceptions that other travellers may have, rather than actual experiences.

“I’ve just never had the confidence to go through the airport with the stimulator on in case they think there’s a bomb.” (Marie, carer)

The most consistently raised concern surrounded the effect on skin, with a number of participants reporting varying issues of skin breakdown. Only one patient had to ration the use of FES to cope with the skin problems.

“But the one thing that I did find after using the pads I had terrible rashes and the skin started to break out” (Paul, patient)
“Well I’ve battled ever since with the pads, I cannot wear the pads, I couldn’t wear the pads all week it would be impossible” (Paul, patient)

Despite this Paul still appreciated the positive role that FES had on his life.

“Even though I’m not using it every day, I still think the benefit is knowing if I’m going for a long walk I can put it (FES) on and get out” (Paul, patient)

**DISCUSSION**

This study contributes to a more detailed understanding of stroke patients’ and carers’ perceptions of the impact of FES in the management of dropped foot. Overall, both patients and carers articulated the positive benefits of using FES after stroke. This is reflected in an emergent overarching theme and four sub-themes. These results provide new and insightful qualitative data on the impact of FES in the management of dropped foot, not only directly on the patient with stroke, but also their carer.

In this study, patients indicated specific benefits from the application of FES. One benefit verbalised by patients related to an improvement in their quality of walking. Similarly carers noted that FES had a positive impact on their partner’s walking although the primary benefits for carers were expressed as increased mobility and a reduced need for walking aids. Previous questionnaire-based studies [Taylor et al, 1999; Taylor et al, 2004] of FES users found that decreased effort was the primary reason for continued use of the device with a hope their walking would improve in
the future. In the current study patients chiefly associated FES with an established improvement in the normal appearance and quality of their walking. Interestingly the participants in the current study had been using FES for substantially longer than those in the previous research [Taylor et al, 1999; Taylor et al, 2004]. The differences in results from the current study compared to previous questionnaire based research may be due to the differing methods of data collection, mixed pathologies and length of time of FES had been in use. Malone et al, 2002, used interviews to explore users and partner’s perspectives of FES in a population of mixed neurological pathologies. FES users identified benefits on walking, namely impact on effort, speed, distance, and normality, similar to those found in patients with stroke in the current study. The direct impact on carers was reported as a greater confidence to leave their relative on their own. The present study has identified in detail the perceived impact that FES, for the management of dropped, has on carers of people with stroke.

In this current qualitative study, participants linked FES to regaining some control over their life. FES was identified as a contributor to returning to social engagement and participation in the local environment. Carers directly associated this increased activity and participation with a reduction in their workload and caring role. Taylor et al, 2004, reported that FES increased the independence of patients and improved their quality of life. The closed questions in that study may have restricted the depth and understanding gained regarding the impact of FES. Conversely, by its design, the current study allowed in-depth exploration of the lived experiences of patients
with stroke and carers on the impact of FES, for the management of dropped foot. Interestingly no other studies have documented the impact FES has on carers and their caring role or workload. From this current research it could be hypothesised that FES has the potential to impact, not only, on stroke patients’ ability to participate and regain control of their lives, but also on those that undertake the caring role. Further qualitative research examining these issues should be undertaken to fully explore the impact that FES technology may have on carers of patients with stroke.

The physical improvements gained, using FES, in this study also had a general positive psychological impact on confidence and mood of both patients and carers. Limited reference has been made to the impact of FES used in the management of dropped foot on mood in previous literature. Taylor et al, 2004, reported that patients were more confident when using FES, but failed to provide any further insights into this psychological benefit. The present study also found an improvement in confidence but additionally provided new insights about the positive impact of FES on the mood of both patients and carers. One carer, however, reflected that whilst FES had direct positive and valuable physical improvements this only served to highlight the disabling nature of stroke and loss of previous life. Further work exploring the psychological impact of FES, in the management of dropped foot, and particularly on carers of patients with stroke, is required to gain a greater insight into this area.
Despite expressing some drawbacks with the FES technology, in this study both patients and carers verbalised that the positives outweighed the negatives. Previous literature has identified a number of issues in relation to FES, namely; skin breakdown, FES set-up and cosmesis [Taylor et al, 1999; Malone et al, 2002; Taylor et al, 2004]. In the current study similar concerns were reported by both patients and carers. Manufacturers recognise many of these issues and ongoing development of this technology is in progress, in particular implantable electrodes [Kottink et al, 2008]. It is interesting to note that despite these problems participants did not deem them to be significant enough to prevent its ongoing application.

In contrast to previous studies [Taylor et al, 1999; Malone et al, 2002; Taylor et al, 2004] who explored populations of mixed pathologies, the current study has allowed in-depth exploration of a specific phenomena; FES, for the management of dropped foot, on a stroke only population, in patients’ and carers’ own words. The recruitment of long term FES users and their carers’ provides a deeper and more global picture of the perceptions and insights of this specific population.

The credibility of qualitative research must be examined to determine the degree of confidence readers can have in the results. The Lothian FES clinic predominately provides FES for the management of dropped foot after stroke and has an identified inclusion criteria for the selection of patients which includes a baseline level of mobility. Patients attending the FES clinic are required to walk a minimum of 10 metres independently. This research therefore explores a very specific stroke
population. Participants were sought from the database of patients attending the Lothian FES clinic and two of the research team were directly involved with the service and this study. This could have led to selection bias. To address these issues and allow an exploration of a diverse clinic stroke population, purposive sampling with a stratification process was applied and undertaken by an independent researcher. The small sample size, of both patients and carers, could be questioned but it is believed that the depth of analysis and findings identified valuable insights that are important in relation to FES and patients with stroke and their carers [Smith, 2008]. A criticism raised in previous literature was the lack of an independent researcher [Taylor et al, 1999; Malone et al, 2002; Taylor et al, 2004]. In order to reduce bias in this study and enhance the validity of the results, an independent researcher with previous qualitative research experience was involved. This ensured that participants were able to freely express their opinions regarding FES. The researcher selected did not, however, have expertise in either stroke or FES. It might be argued that the lack of understanding of the topic area could have impacted on the richness of the data collected. Study rigour was enhanced by the use of an independent research assistant, and verification of participant interview summaries. Interestingly, the results concur with previous published data [Taylor et al, 1999; Malone et al, 2002; Taylor et al, 2004] but all currently available results relate to dedicated FES services. The transferability of these results to stroke populations receiving FES for the management of dropped foot out with a clinic structure could be questioned.
This study offers the opportunity to gain a greater insight and understanding into the impact that FES has on both patients with stroke and their carers in the management of dropped foot. Overall, FES impacted positively on important aspects of their lives including walking, psychological and control of life. Drawbacks with the technology were highlighted but did not detract from the benefits of FES for the management of dropped foot. Due to the limited published data in this area additional research exploring the benefits of FES in a larger stroke population would be beneficial to verify the integrity of these results. In particular, research exploring the impact of FES on carers of patients with stroke, including the psychological influence, is required. It is also recognised that the population under exploration received FES from a dedicated FES clinic. Therefore the transferability into a general stroke population, receiving FES for the management of dropped foot as part of routine clinical intervention, is limited. Further quantitative and qualitative research in this general population would be of value.

**CONCLUSIONS**

This study provides insights into the perceptions of patients and carers of the impact of FES. These results have implications for clinicians delivering an FES service for the management of dropped foot after stroke. These robust results enhance the evidence base for the use of FES for the management of dropped foot in stroke and provide further avenues for research.
CLINICAL IMPLICATIONS

- This qualitative study provides clinicians with a greater insight and understanding of the impact FES for the management of dropped foot has on patients with stroke and their carers beyond that identified from quantitative research alone.
- Patients with stroke and their carers greatly valued the positive impact that FES had on their walking, mood and control of their own lives.
- FES should be considered as a treatment option for the management of dropped foot after stroke.

Acknowledgements

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Declaration of interest

The authors report no declarations of interest.
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Table 1: Interview guide

<table>
<thead>
<tr>
<th>FES components of Interview Guide</th>
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<tr>
<td>• How do you use FES in your daily life?</td>
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<td>• How did you find learning to use it?</td>
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<td>• What did you think of FES as a strategy?</td>
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<td>→ prompts / probes: how did it affect your life? How did you feel about that?</td>
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<td>• How did it affect the way you spent your time?</td>
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<tr>
<td>→ prompts / probes: such as social activities, work, looking after yourself</td>
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<tr>
<td>• Were there any particularly positive things about it that stick out in your mind?</td>
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<td>• Were there any particularly negative things about it that stick out in your mind?</td>
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<td>• Does your leg feel different at all?</td>
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<td>→ prompts / probes: How does that affect you?</td>
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<td>• How has it affected your walking in particular?</td>
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<td>• Now that you've been using FES for more than six months, what support do you receive?</td>
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<td>• How does that affect you?</td>
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<td>• How much support would you like to receive?</td>
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<td>• Is there anything you feel you need that you do not receive at the moment?</td>
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<td>Pseudonyms</td>
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