

An exploration of the experiences and utility of functional electrical stimulation for foot drop in people with multiple sclerosis.

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➤ **Implications for Rehabilitation**

- People with Multiple Sclerosis using functional electrical stimulation report benefits in many aspects of walking, improved psychological well-being and increased engagement in valued activities.

- A number of challenges impact on functional electrical stimulation use. Factors such as; a positive experience using the device, access to professional help, the influence of others, a strong sense of personal autonomy and an individual's ability to adapt, influence an individual's decision to continue using functional electrical stimulation.
- Clinicians prescribing functional electrical stimulation should be aware of these factors so that the right support and guidance can be provided to people with Multiple Sclerosis, thus improving outcomes and compliance over the long term.

Abstract

Purpose: Functional electrical stimulation is effective in improving walking in people with Multiple Sclerosis with foot drop. There is limited research exploring people's experiences of using this device. This study aims to explore the utility, efficacy, acceptability and impact on daily life of the device in people with Multiple Sclerosis. *Methods:* An interpretative phenomenological approach was employed and analysed interviews from ten participants who had used functional electrical stimulation for twelve months. Transcripts were analysed, and emergent themes identified. *Results:* Nine participants continued to use the device. Three relevant super-ordinate themes were identified; *Impact of functional electrical stimulation*, *Sticking with functional electrical stimulation* and *Autonomy and control*. Participants reported challenges using the device, however all reported positive physical and psychological benefits. Intrinsic and external influences such as; access to professional help, the influence of others, an individual's ability to adapt, and experiences using the device, influenced their decisions to continue with the device. A thematic model of these factors was developed. *Conclusion:* This study has contributed to our understanding of people with Multiple Sclerosis experiences of using the device and will help inform prescribing decisions

and support the continued, appropriate use of functional electrical stimulation over the longer term.

Introduction

Multiple Sclerosis (MS), a chronic inflammatory demyelinating disease of the central nervous system presents with a variable disease course and an accumulation of disability over time [1]. Walking impairment is common in MS and around 85% of people with MS report problems with gait as their primary complaint [2]. Walking impairment has been found to impact negatively on employment status and ability to perform activities of daily living [3,4]. In addition, people with MS identify the impact of MS on lower limb function and walking as their greatest concern [5].

Foot drop, presenting as a reduction in dorsiflexion at heel contact and during the swing phase of gait, is commonly observed in MS. There are no exact estimates for its prevalence. Foot drop in MS results in a reduction in the speed and effort of walking [6-9] and contributes to an increased risk and fear of falling [10]. Subsequent debilitating consequences such as activity reduction, social isolation, immobility and deconditioning have been reported [11].

Assistive technology can be used to manage foot drop in MS and other neurological conditions. Functional electrical stimulation (FES) devices apply electrical stimulation to the common peroneal nerve which contracts the dorsiflexor muscles of the ankle, thus assisting with foot clearance during the swing phase of gait [12]. Stimulation can be applied externally or internally via implantable electrodes (STIMuSTEPTM, Finetech Medical Ltd, Welwyn Garden City, UK) and is synchronised with gait by using either a pressure sensitive heel switch (e.g. ODFS[®] Pace, OML., Salisbury, UK), a foot switch sensor (e.g. NESS L300[®],

Bioness Inc., Valencia, CA) or tilt sensor technology (e.g. WA[®], Innovative Neurotronics., Austin, Texas, USA) [13]. Single channel devices which stimulate dorsiflexion of the foot are primarily used in people with MS presenting with foot drop, however dual channel devices (e.g. O2CHS, OML., Salisbury, UK) are available where more than one muscle group require stimulation to assist with walking.

The orthotic effect of FES has been well documented and is described as the difference between the device being switched on or off [14]. A recent systematic review and meta-analysis reported clinically meaningful orthotic effects of FES on gait speed in MS [14]. In addition, there is growing evidence of positive orthotic effects of FES on kinematic aspects of gait [15-17].

Assistive technologies (AT) such as FES are designed to improve function, enhance independence and enable an individual to successfully live at home and participate within their community. A better understanding of a user's experience is critical to improving the compliance with, and acceptance of AT interventions, thus enhancing individuals' quality of life [18].

A number of FES studies have found a positive impact on a range of self-reported walking and quality of life measures in MS [19-22]. Furthermore, FES has been perceived as an effective device to improve walking distance and reduce the risk for falls in MS [21,22]. Two retrospective studies using postal questionnaires investigating patient satisfaction reported improved confidence and a reduction in effort of walking as key motives for continued use of FES [23,24]. Difficulties nevertheless with electrode positioning and equipment reliability were cited as significant barriers to long term use [23,24].

To date, only one qualitative study using a focus group methodology, compared the experiences of two devices, ankle foot-orthoses and FES, in MS [25]. Participants in this

study described positive benefits with FES such as; a reduction in trips and falls, improvements in fatigue and distance walked and an increase in confidence, fitness and participation and engagement in physical activity. Barriers such as implications for clothing and difficulties in the application and wear of FES were highlighted, although participants felt the positives outweighed the negatives. Participants in this study were recruited from two different studies and had used their devices for variable time periods of up to two years. Moreover, this study did little to explore the impact of FES on the psychological and social aspects of device use, thus further high quality qualitative research is required in order to understand such experiences. This will undoubtedly aid clinical decision making, increase patient satisfaction, and enhance usage and efficacy over the longer term. Furthermore, understanding and addressing barriers to FES use will assist in future development of the device, thus optimising compliance and the implementation of FES for people with MS and other neurological conditions. This study therefore aims to explore people living with MS experiences of FES focusing on its utility, efficacy, acceptability and its impact on daily life.

Materials and Methods

Study design

In depth telephone interviews were carried out with ten participants who had used FES for twelve months. This study was as an integral part of a randomised trial comparing the effects of two devices (FES (ODFS[®] Pace, OML., Salisbury, UK) and ankle foot-orthoses) for foot drop on the speed and oxygen cost of walking, fatigue, falls, activity levels and quality of life in MS. Ethical approval for this study was granted by the West of Scotland Research Ethics committee 4 (14/WS/0014). The baseline results of the effect of both devices on the speed and energy cost of walking have been presented elsewhere [26]. Ten participants were selected from forty two participants who had consented to participate in the study and had

been randomised to receive FES. Participants were recruited from seven health board areas across Scotland; Ayrshire and Arran, Dumfries and Galloway, Fife, Greater Glasgow and Clyde, Lanarkshire, Lothian and Tayside and gave their informed written consent to participate in the study.

Participants were included if they had; a clinical diagnosis of MS, stable MS (no change in disability over previous three months), persistent foot drop observable during a five minute walk test, and no changes to medication or rehabilitation over the previous three months.

Participants who had; previously used ankle foot-orthoses or FES for foot drop, presented with another neurological, respiratory or musculoskeletal condition significantly impacting on gait, moderate to severe cognitive impairment (scored < 26 Montreal Cognitive Assessment test) or other significant MS impairments impacting on gait were excluded from the study.

An interpretative phenomenological analysis approach was used in order to undertake an exploration of the individuals lived experience and attempt to understand their relationship with the phenomenon of using FES [27].

Participant characteristics

Of the ten participants recruited four were male and six were female (table 1). Participants were from five of the seven recruiting health boards. Four participants presented with relapsing remitting, three with secondary progressive and three with primary progressive MS. Disability ranged from 3 to 6.5 on the Extended Disability Status Score and time since diagnosis ranged from three months to seventeen years.

Participants (pseudonyms)	Sex	Recruitment Centre	Age	MS type	EDSS	Time since	Employment status	Living with
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						diagnosis (years)		partner
Maggie	F	4	66	RR	6.5	17	Retired	√
Brian	M	2	47	PP	6.5	0.3	FT	√
Gillian	F	2	44	SP	6	17	Med R	√
Alison	F	3	40	SP	6	2	Med R	√
John	M	1	60	SP	3	0.3	PT	√
Peter	M	3	39	RR	3.5	5	FT	X
Susan	F	4	41	RR	3	15	FT	√
Joanna	F	1	43	RR	6	0.2	PT/Off sick	√
Colin	M	5	58	PP	3	13	Med R	√
Karen	F	2	44	PP	4.5	0.4	FT	√
Mean	F:M,6:4		44.2		4.8	7.2		

Table 1: Participant characteristics (Abbreviations: EDSS; Extended disability Status Score, F; female, M; male, RR; relapsing remitting, SP; secondary progressive, PP; primary progressive, Med R; medically retired, FT; full time, PT; part time)

Procedure

Ten participants from a total sample of thirty one who had been issued with FES and were still using the device at the end of the twelve months trial were identified. Quota sampling was used to select participants by applying the characteristics of; sex, disability level and recruitment centre, in order to recruit participants who were representative of the entire sample. After their last assessment visit participants were approached by the research physiotherapist (AL) and invited to participate in a telephone interview. Following verbal consent their contact details were passed to the chief investigator (LMR), who had not been involved in either delivering the intervention or undertaking assessments in the main study.

An interview topic guide was developed prior to undertaking the semi-structured telephone interviews. Questions were designed to be open and expansive, free of assumptions and implied values, and not leading. Verbal input from the interviewer was kept to a minimum, thus encouraging narrative and evaluative sequences from the participant. The interviews

were conducted between 19/08/2016 and 18/05/2017 and lasted between 18 and 42 minutes. The interviewer had an expert understanding and clinical experience of MS, the management of foot drop and FES and aimed to take the objective position at all stages to gain a fuller understanding of the experiences and views of participants.

All interviews were digitally recorded using a password protected device and recordings were stored according to data protection legislation. The researcher recorded reflective notes which were referred to during analysis. Interviews were transcribed verbatim and all audio files were deleted immediately thereafter. The names of the participants were changed to pseudonyms to protect confidentiality.

Analysis

Interpretative Phenomenological Analysis commits itself to an in depth examination of how individuals make sense of their life experiences [27]. Each transcript was analysed individually by the main author (LMR) which involved exploratory commentary examining the descriptive, linguistic and conceptual content of the data. Analysis of the exploratory comments was then undertaken, and emergent themes were identified for each participant [27]. The second author (PF) audited the data at each stage of analysis. Subsequent analysis of the recurrence of emergent themes identified three super-ordinate themes which were directly relevant to the aim of the study.

Results

Summary of analysis

The analysis detailed three super-ordinate themes which provide a structure for the paper; *Impact of FES, Autonomy and control* and *Sticking with FES* (table 2).

Participant initials	M	B	G	A	J	P	S	L	C	K	Total
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1. Impact of FES	√	√	√	√	√	√	√	√	√	√	10
Improving aspects of walking	√	√	√	√	√	√	√	√	√	√	10
Facilitating connections with the conscious control of walking	√		√	√				√	√		5
Facilitating choice in meaningful activity and participation	√	√	√	√	√	√	√	√	√	√	10
Impact on emotions, outlook and mental well being	√		√	√		√	√	√	√	√	8
2. Sticking with FES	√	√	√	√	√	√	√	√	√	√	10
Early days: getting into a routine	√	√	√	√	√	√	√	√	√	√	10
Developing strategies and adaptations	√	√	√	√	√	√	√	√	√	√	10
Professional help at hand	√	√		√			√		√	√	6
Weighing up the pros and cons	√	√	√	√	√	√	√	√			8
Persevering with FES	√	√	√	√	√	√	√	√	√	√	10
Forming a relationship with FES	√		√	√	√					√	5
The Influence of others	√	√	√	√	√	√	√	√	√	√	10
3. Autonomy and control		√	√	√	√	√	√		√	√	8
Locus of control		√	√		√	√	√		√	√	7
Personal autonomy and choice		√		√		√				√	4
Self-determination				√		√	√		√		4

Table 2: Occurrence of the three super-ordinate themes and subthemes across participants (M, Maggie; B, Brian; G, Gillian; A, Alison; J, John; P, Peter; S, Susan; L, Lesley; C, Colin; K, Karen).

Impact of FES

Four subthemes were identified within the super-ordinate theme of *Impact of FES* and are presented in table 3.

<p>Impact of FES</p> <ul style="list-style-type: none"> • Improving aspects of walking • Facilitating connections with the conscious control of walking • Facilitating choice in and sustaining activity and participation • Impact on emotions, outlook and mental well being

Table 3: Super-ordinate theme and subthemes; Impact of FES

The impact of FES on *Improving aspects of walking*, the first subtheme, was discussed by all the participants. The degree of benefit was significant for some participants. Comments such as “the device was excellent”, “improved my walking 90%, without a doubt” and “the improvement was absolutely phenomenal” were common throughout the data. Participants felt many aspects of walking had improved using the FES device. The most commonly reported were a reduction in trips and in the worry relating to trips and falls when walking. John described this and said “unbelievable, the amount of relief it gives that you don’t have to worry that you’re going to trip yourself up”. Participants frequently reported they could walk quicker, further and with reduced effort with FES. Improvements in the quality of gait and in balance, reduced dependency on walking aids and a reduction in levels of fatigue were also reported.

Despite the majority of discussions being mostly positive, a few participants found that FES wasn’t helpful on stairs and escalators. Others found that although FES was helpful initially the effects did not last when walking for longer distances. An orthotic effect of FES was commonly described, and most participants reported this as ongoing, although some observed an immediate effect.

Colin describes the extraordinary difference that FES has made and how his walking now is in complete contrast to how his walking was without the device. This effect was evident from the first moment he used FES:

“All I can say is, from day one, when I was given it, the improvement in my walking was like chalk and cheese. I didn't realise how little lift I had in my foot until the device was fitted. I can't say enough about how much I think this has benefitted me. It really has, without a doubt.”

FES was found to be key in *Facilitating connections with the conscious control of walking* by around half of the participants. Participants spoke about not having to “concentrate as hard” or “having to think about every step they were taking” when using FES.

Gillian describes the mental effort previously required when walking and how the FES device has taken over some of this conscious control:

“Before, I mean I was very self-conscious as I said about the way I was walking, about tripping, about catching my toes. And you know I, I was constantly thinking about whether I’m lifting my leg up high enough or having to swing it. And you know, that almost, taking away, or that kind of thing, because the device was doing the thinking for me.”

The positive impact of FES on *Facilitating choice in meaningful activity and participation* was reported by all participants. For some people this meant that “everyday life was more comfortable”, however for John, he found that he had to completely rely on FES to help him through his working day. He said “without it, I can’t operate without it. I couldn’t go to work.” The majority reported that FES facilitated engagement in a range of social, leisure and vocational activities such as; shopping, gardening, cooking, walking the dogs, accessing public transport and leisure pursuits such as holidays. Some participants found that FES was beneficial going up steps and stairs, which was in contrast to other participants experiences.

In addition to observable physical benefits most participants reported a positive *Impact on emotions, mental well-being and outlook* with FES. Increased confidence was most frequently reported. For some participants however, FES appeared to act as a catalyst for positive change, impacting at both psychological and social levels.

Karen recounts that the difficulties she was having with walking prior to receiving FES were insidiously affecting her confidence, self-image and self-esteem. There is a sense that it is

deeply important to her that she is able to walk in a way that was accepted by her and others as normal. She expresses a complete lack of control over how MS was affecting her walking. FES appears to have exceeded her expectations and this positive impact has affected unanticipated aspects of life such as her whole mental wellbeing:

“ As I’ve said it’s made such an incredible difference to my life, it really has. Little did I know that when I went in, I thought I was getting something to help me walk a little bit better but actually, it would change so much else. I think for me, that negativity that had started to creep into my life about my walking and my self-consciousness about my walking that I would never be able to walk properly again. I have no doubt that could have very easily spread and become something that became an issue across loads of other areas. I think I’ve been given an opportunity to be in this study and for that to be nipped in the bud for me, from a mental health perspective I think is just amazing”

Lesley also describes a deep desire of a return to normality. The FES device has allowed her to feel equal with others and helped her to re-establish a positive sense of identity:

“ I did actually feel normal walking just like everybody else in the high street. And you actually felt that you were walking the exact same as them, even though you were getting, helping to do it. But em, I don’t really know how to explain it, just like being normal again, you know what I mean, just like being an everyday person out walking about.”

Sticking with FES

Six subthemes were identified within the super-ordinate theme of *Sticking with FES* (table 4). At the time of the interviews, following twelve months use, nine of the ten participants continued to use FES.

Sticking with FES

- **Early days: getting into a routine**
- **Developing strategies and adaptations**
- **Professional help at hand**
- **Weighing up the pros and cons**
- **Forming a relationship with FES**
- **The Influence of others**

Table 4: Super-ordinate theme and subthemes; Sticking with FES

The first subtheme, *Early days: Getting into a routine* was reported by all participants.

During the first few weeks and months many practical difficulties were highlighted such as; getting accustomed to the stimulation, applying the electrodes in the correct place, getting the equipment organised and using and wearing the device in daily life. Often participants reported that it took many months before feeling confident applying and using the device.

Over time participants developed their own ways of adapting to using FES by wearing different clothing and deciding when they would use the device. This is described in the second subtheme, *Developing strategies and adaptations*.

Susan saw this as an exciting challenge and responded in a positive way by embracing new ways of dressing to accommodate the FES device:

“It’s made me look at dressing myself differently em and so I wear my clothes in a whole different way... Again, this was quite interesting and exciting... I wear socks a lot more now, I em don’t wear tights, hardly ever. Em because I found it was easier to apply the electrical stimulator em cos you’ve got one attached to your leg. Em so I’d wear that with the socks and....what are they called, leggings that only come down to my knee. And then the other wire would go over the top of that, and then I would put on a skirt and a pair of boots”

Participants were initially instructed to use FES on a daily basis and to build up their wear time. Most participants used FES every day, a few used it most days and a few used it a couple of times a week. It was clear that if participants experienced positive benefits from using FES during certain activities, they were likely to subsequently choose to use FES during these activities.

Gillian describes putting the FES device on every day, but specifically switching it on to help with walking the dogs and shopping:

“It was on a daily basis, yeah. I never used it much when I was just in the house but if I knew I was going somewhere or whatever the, the device would go on and it would be on all day....So yeah, it was used on a daily basis and if I was going shopping sort of thing during the day I would put it on in the morning but if I was just in the house I wouldn't use it until basically I was going for my walk at night with the dogs”

A few of participants mentioned problems with skin irritation from the electrodes and this impacted on how often they used the device.

John describes how he rationed the use of his device in order to manage this problem. He focused on using the FES device for activities that were most important to him, ultimately choosing to use it to help him get through his working day. There is a sense that he feels that FES has now become an essential part of his daily working life:

“When I'm in the house on my days off and things like that I don't put it on. I walk about the house, so it doesn't irritate my leg too much and it can help me sometimes if I've come in from work and Irene wants something done in the garage. Yes, I'll keep it on cos I feel I can walk a bit better..... It's on every day for 4 hours at work each day and an hour to get there and back..... It's just part and parcel of the day to day workings now.

Electrodes on if I'm going out, electrodes off if I'm staying in. I can't go out without them"

Professional help at hand, was discussed by most participants. Participants felt that quick access to professionals who could give advice about managing skin reactions and electrode positioning in addition to help with faults and repairs facilitated them *Sticking with FES*.

Weighing up of the pros and cons of FES was a subtheme identified by the majority of participants. It was evident that a number of practical difficulties with electrode placement, the sensation of the stimulation, the time for set up and having to adapt clothing and footwear influenced whether participants decided to continue with FES or not. Participants verbalised a balancing of positives and negatives such as "the benefits outweighed the positives" and "there's pros and cons but if it helps your walking it's a big pro".

Lesley describes how she overcame some of the drawbacks of FES with perseverance and how the positive impact on her walking overshadowed some of the remaining negative aspects, helping her to continue with the device:

"It is sore (both laugh). Em it is a bit uncomfortable to begin with. Yeah, it does take a bit of time to set up and that, but once you know what you're doing em and you know exactly where you've to put your pads and everything eh it's, it is easy. I suppose it's difficult to begin with cos it does look really complicated and everything but once you get the hang of where it's supposed to go and where, how you've to set it up and everything, it is easy enough. There is pros and cons but if it helps your walking it's definitely a big pro."

Peter, the only participant who decided not to continue with FES, did report some benefits. However, he considered the benefits to be minimal in comparison to the time and effort required for set up, and this ultimately swayed his decision not to continue with the device. He described the choice as a "cost benefit analysis":

“Time consuming, time consuming, that’s what I’m saying. The time, time consuming cost I had to set aside 20 minutes before I went out the door in order to make sure that it was set up correctly... .. I’ll stress this again, and I know everybody is not the same, this is only my individual circumstances. The benefit, what it gave me was a small benefit, but in order to get that small benefit I had to, there was a substantial amount of time needed on my part which wasn’t worth it.”

As participants gradually developed their own strategies, some gave the FES device itself a new identity which was sometimes integrated with their own identity. *Forming a relationship with FES*, was a strong recurrent theme for a few participants. Maggie recounts how both her and her husband now refer to “her leg” being switched on or off rather than the FES device itself. This creates the impression that FES is no longer separate but is a cohesive aspect of her identity. Both Karen and John talk about the FES device becoming their friend and ally. Karen says of FES, “every day, it’s me and my pal”. By accepting and viewing the device as a friend, it is evident that this has helped her to stick with FES over the longer term. Having trust, confidence in and reliance on the FES device was very much part of the relationship these three participants had formed with FES. Participants trusted and expected the device to assist in tasks which they were no longer able to accomplish on their own.

John describes how he initially viewed the FES device as being alien and as the enemy. Through time however, he developed a new relationship which he viewed as a positive partnership of which he is highly appreciative:

“Well this little alien is helping me a lot. It’s a very helpful alien, a very helpful Klingon shall we say..... this little Klingon, it’s clung on and will be clinging on for a long time (laughs). So, I can’t do without this little Klingon (both laugh). Sorry I’m a big star trek fan.....The Klingon’s were baddies. They were baddies, but as star trek goes on they

become friends and they're not aliens anymore they're partners in the universe. So, this is a partner. So, I'm very grateful for this little machine, my new little Klingon (both laugh). Very, very grateful."

The influence of others was a subtheme which was interwoven throughout all of the interviews. Participants were influenced by other opinions, especially close family members, others using FES and professionals, with regards to their decisions to continue with FES or not. A few participants discussed the influence of work colleagues. When asked what they would recommend FES to other pwMS who had foot drop to try FES, all of the participants said that they would.

Karen is enthusiastic in her recommendation of FES. It is clear that she feels that others could benefit as she has by just taking a risk and trying FES:

"Definitely try it. Without a doubt, anybody that's got this sort of foot drop thing, if they've got an issue with walking, I would say to them, "If you can get hold of one of these gadgets and even just try it for a little while, you've got to see the difference in the way you can walk and lift your foot." without a doubt, "Give it a try..... you've got nothing to lose. At the end of the day, if it's not for you, you can take it off and go back to what you were doing."

Autonomy and Control

Three subthemes were identified within the super-ordinate theme of *Autonomy and Control* (table 5).

Autonomy and control

- | |
|---|
| <ul style="list-style-type: none">• Locus of control• Personal autonomy and choice• Self-determination |
|---|

Table 5: Super-ordinate theme and recurrent themes; Autonomy and control

Locus of control was identified in most of the interviews. The concept of locus of control refers to an individual's perception about the underlying causes of events in his/her life [28]. Individuals with an internal locus of control generally believe that success or failure is attributed to their own efforts, whereas those with an external locus of control believe that external factors dominate the outcome of events. Some participants described relying on FES to take over aspects of their walking. This could be viewed as a switch from an internal locus of the control of walking to one of reliance and dependency on an external device. Some participants also described that the FES device “was doing the thinking” for them. This implies a sense of machine agency, where the FES device was no longer just a passive participant but performing an activity of a personal nature dependant which is dependent on trust. John describes this below:

“I was constantly thinking about whether I’m lifting my leg up high enough or having to swing it. And you know, that almost, taking away, or that kind of thing, because the device was doing the thinking for me”

A few participants discussed how FES restored a sense of *Personal autonomy and choice*, particularly when they spoke about their decisions to stick with FES or otherwise.

Karen describes how using the FES device profoundly transformed her mindset and changed her perspectives on how to live life with MS. It is clear that an internal locus of control and greater sense of personal autonomy has been restored:

“I probably, before the device, had started to enter a bit of an “I can’t” mode in terms of doing stuff..... I was back into “we can do this, we can go for a walk around the park, we can go out with my wee girl.”

Self-determination was evident in a few of the participant interviews. *Self-determination* is described as an individual's ability to make balanced decisions without undue external influence [29].

Following the positive experience of using FES, Alison expresses some of the skills of *self-determination* such as self-assertiveness, self-advocacy and pride, and commits herself to make FES work. She is clearly driven by her sense of self-dependency and reliance:

“Just because it felt so, I felt so much better with it on I just thought to myself, I have to make this easier for myself. So I, once I knew what I was doing I went back to Anna [physiotherapist], then I was putting the pads in the right position and everything, once I got all of that sorted well just because I am just on my own I can only rely on myself so I had to say “come on Alison, get it sorted, now get that [laugh], get that sorted” so then I just had to do it, there was no other way about it. I’ve only got myself to rely on, so can only count on myself”

Although Peter decided to discontinue with FES, he displays a strong sense of self-determination in his decision making. He demonstrates a resolve to take charge of his life by evaluating his options and making choices without external influence and interference. Peter exhibits many of the attributes of self-determination such as self-awareness, pride and problem solving skills:

“I gave it a try for a good while, off and on and eh returned to it every so often and came to the same conclusions..... I sat down and said “well if I’m ok, I managed that fine without the device, eh if I can manage 2 days in Edinburgh in those circumstances you know pretty constant, em 1 day after another, then I can manage that, I’ve not really got enough problems to justify wearing the device.”

It is clear here that aspects of both Alison and Peter's personality drove their decisions about *Sticking with FES* or not over the twelve months.

Discussion

This study found that pwMS presenting with foot drop reported both immediate and ongoing benefits using FES. Improvements in many aspects of walking, increased participation in valued activities and a positive impact on emotions, outlook and mental well-being were discussed by the participants. Some limitations of FES were noted, however after twelve months, nine of the ten participants continued to use their device. A number of factors influenced pwMS ability in *Sticking with FES* and a model of the relationship between these factors has been developed.

Only one qualitative study has previously evaluated the experience of six participants with MS using FES [25]. Bulley et al. [25] reported a reduction in trips, falls and fatigue and improvements in the speed and distance of walking which were similar to those found in the current study. These benefits have also previously been reported in quantitative studies [9, 14, 16, 17, 19, 20, 23]. Bulley et al. [25] reported a reduced mental effort of walking with FES. Results from the current study however went beyond those of Bulley et al. [25] and identified the subtheme of *Facilitating connections with the conscious control of walking* with FES. In order to participate in social, leisure and daily activities, individuals need to be able to walk whilst simultaneously engaging in other tasks. Wajada et al. [30] found that gait speed reduced when people with MS engaged in cognitive tasks. Ciol et al. [31] found that people with MS struggle to simultaneously engage in cognitive and motor tasks thus affecting mobility. Finlayson [32] suggests that disorders in sensory-motor function, working memory and attention contribute to people with MS requiring to increase conscious control and concentration, particularly in dual-task activities. This can lead to a deterioration in the

performance of tasks [32], higher levels of physical and cognitive fatigue and an increased falls risk [33]. Although the mechanisms involved are not understood, FES has previously been found to strengthen activation of motor cortical areas and their residual descending connections in MS [34]. The results from this study suggest that FES may have the potential to reduce the cognitive burden of walking, however further research to explore the possible mechanisms involved is required.

Souza et al. [35] reviewed the impact of AT mobility devices used with people with MS and reported improved independence as the main benefit. The current study found that FES facilitated increased engagement in activities which were similar to those described by Bulley et al. [25]. Some participants in the current study also described a restoration of self-efficacy, which is essential in maintaining motivation. Up to 80% of people with MS do not participate in any meaningful physical activity [36], including **activities of daily living** and leisure pursuits. Physical activity has a role to play in maintaining function and health in pwMS [37, 38] and the findings from this study suggest that FES can facilitate increased engagement in a range of activities, which has the potential to enhance levels of physical activity in people with MS. Further research examining the impact of FES on physical activity is required in order to fully understand the wider potential benefits on health, physical function and quality of life.

The current study identified the enhancing influence of FES on *Emotions, outlook and mental well-being*. These findings suggest the transformative potential of FES beyond an increase in confidence and reduced anxiety in walking described by Bulley et al. [25]. Some participants described a shift in their perceptions of the locus of control of walking, from self to FES. For others, FES facilitated recovery of some aspects of self-esteem, self-worth and positive self-image and expedited a return to their previous functioning. Korwin-Piotrowska et al. [39] found that people with MS often present with low self-esteem, decreased self-acceptance,

resignation and despair which can result in individuals restricting or withdrawing from activities. Many salient aspects of self can be lost as a consequence of MS such as one's view of self as being an active, independent and capable person, thus being replaced by negative self-concepts [40, 41] and this was expressed by many of the participants in the current study. The findings suggest that FES can play a positive role in supporting people with MS in the challenging process of role/identity re-examination and adjustment.

Although FES has the potential to reduce many of the negative impacts of MS, previous research has found that large numbers of AT devices are abandoned within the first year of use [42, 43]. Initial FES start-up costs are generally high but vary depending on the device purchased. FES has been found to be cost effective in patients with central nervous system disorders [44]. Nevertheless, cost-effectiveness could be further improved with greater device compliance, allowing the benefit of treatment to accrue over time. It is important therefore to consider the factors influencing adherence both from a cost effectiveness and personal outcome perspective. Squires et al. [45] explored the experiences and perceptions of people with MS, their carer's and therapists of using a range of AT devices. This study found that service, personal, device and external factors were key in determining continued use [45]. The current study identified a number of recurrent themes which influenced participants perseverance with FES and a model of interaction is described in Figure 1. Access to professional help and the influence of significant others were key aspects of support. Aspects of personality and an individual's ability to adapt and develop their own strategies need to be considered if success in establishing a routine with FES can be achieved. Positive experiences of using FES and forming a beneficial relationship with the device contribute to decisions around FES use. Aspects of personal autonomy facilitate weighing up the pros and cons of FES, which ultimately impacts on an individual's decision to continue with FES.

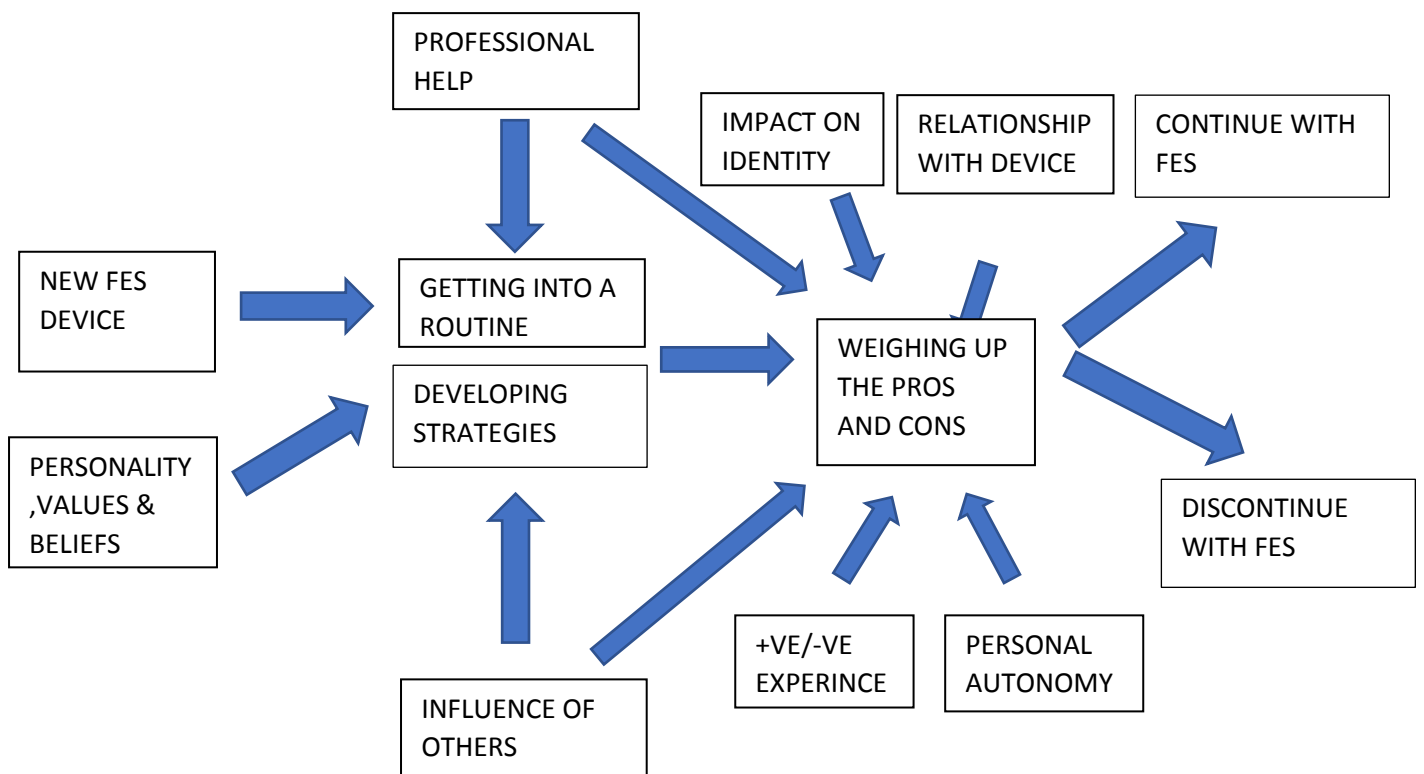


Figure 1: Model of relationship between factors which influenced participants continue with FES (or not) which was supported by the findings.

Many aspects of FES wear and use were found to be challenging. Getting used to the sensation of the stimulation, applying the electrodes in the right place and the time it took to set up the device were frequently mentioned and have been reported elsewhere [23-25].

Participants discussed *Developing strategies and adaptations* to help them get into a routine with FES. Squires et al. [45] suggests that AT can assist in the process of illness self-

regulation, thus contributing to successful adjustment at times of change in MS. External influences such as family involvement, social support and the role of healthcare service were found to influence AT use [42, 43, 46]. *Professional help at hand* and the *Role of others* were subthemes identified in the current study, both of which influenced a participant's ability to settle into a routine with FES. Marini & Stebnicki [47] suggest that the characteristics of the setting must be considered when matching individuals with AT and they advocate that an environment which is supportive and rewarding of AT is essential for continued use. This requires significant others to be on board with device use, in addition to skilled professionals providing a responsive service [48]. These findings were also evident in the current study and therefore need to be considered when supporting individuals in using FES over the longer term.

Personal characteristics, such as internal optimism [48], motivation, positive coping styles, values and beliefs in technology use, patience and self-discipline [47] are key in the continued use of AT. Although this study did not specifically examine personality, there was evidence from the findings that many of the participants demonstrated such characteristics.

Participants in the current study described a process of *Weighing up the pros and cons* before making a final decision to continue with FES. One participant, who decided not to continue with FES, described this as a 'cost benefit analysis'. Squires et al. [45] describe a self-regulatory reappraisal process that people with MS go through with AT use. If an individual experiences a positive outcome, where physical and psychological needs are met following use, the individual is more likely to continue using their device [45]. In the current study the positive impact of FES on self-esteem and identity in addition to facilitated engagement in valued activities met both the physical and psychological needs of nine of the ten participants, influencing their decision to continue using their device. Some participants in

the current also displayed a strong sense of *Self-determination* which drove their decisions.

Due to the ever changing nature of MS, acceptance of FES is likely to be not fixed but cyclical in nature. Regular monitoring of the physical and psychological responses to/outcomes of FES is therefore required in order to support continued use.

A few participants in this study formed strong partnerships with FES. This was a surprising finding and has not previously been described in FES research. It is challenging to consider that a relationship between a person and a device can exist. If such a relationship exists there can be no reciprocity with regards to respect, mutual understanding and goals, all of which are central to genuine partnerships. Engen et al. [49] propose that machine agency facilitates the development of human to machine trust which is essential in enabling the full potential of technology. Some participants spoke about their FES device “doing the thinking” for them. This implies more of an active interaction between participants and the device, which is based on trust. Eply et al. [50] describes anthropomorphism as the tendency to infuse the deeds of objects with humanlike characteristics and proposes that this can occur when an individual is trying to make sense of the behaviour of the object. This theory might explain the relationship that both Robert and Karen developed with their FES device. By perceiving FES as an object that can be trusted, they were able to make sense of their device and to establish a partnership which contributed positively to their new identity. Further investigation is however required in order to understand the impact of machine agency on an individual’s acceptance of and long term compliance with FES.

Strengths and Limitations

In addition to exploring the experiences of people with MS using FES for foot drop this study has provided a model to explicate why people with MS continue to use FES. Participants in the current study however were recruited only if they were still using the device at twelve months and this has contributed to self-selection bias. Thirteen participants from the total

number of participants randomised to receive FES discontinued using their device at various stages over the twelve months. This was less than the group receiving the ankle foot-orthoses, where nineteen participants dropped out, and sixteen of those were due to issues with their device. Six from the FES group dropped out due to device related reasons. Reasons for discontinuing with FES included; increased neuropathic pain (n=1), no longer effective, or no longer required (n=5). The other seven participants were either lost to follow up (n=2), no longer able to commit to the study (n=4), or unable to participate due to disease progression (n=1). This provides some context to why people with MS discontinue FES, nevertheless future research should seek to understand the experiences and views of those who choose not to continue in order to fully understand the reasons why people continue with FES or not. The lead researcher (LMR) is an expert in MS and FES, however has limited previous experience in qualitative data collection and analysis. A second researcher (PF) however was involved in guiding the data collection and analysis and is an expert in the field of Interpretative Phenomenological Analysis research. This therefore gives assurance that the findings demonstrate good credibility [51] and rigour [52].

This study aimed to explore the experiences of people with MS presenting with foot drop and found positive benefits in many aspects of walking, improved psychological well-being and increased engagement in valued activities with FES use. Despite challenges getting to grips with using the device, nine of the ten participants continued to use FES at twelve months. Both intrinsic and external factors affected participants' decisions to continue with the device. The participants own experiences using the device, enabled them to weigh up the physical and psychological benefits of FES against any challenges they had experienced. It is important to understand why people decide to begin, adapt and continue their use of FES, from both a cost effective and personal outcome perspective, so that interventions can be further developed and evaluated. Such interventions should work for both people with MS

and health care professionals to assure their uptake, compliance and effective implementation. This study has contributed to our understanding of people with MS experiences of getting to grips with using FES during its first year of use. This will help inform prescribing decisions and support the continued, appropriate use of FES over the long term, increasing patient satisfaction and efficacy.

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Declarations of Interest

The authors report no declarations of interest

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