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**A nation-wide survey exploring the views of current and future use of
Functional Electrical Stimulation in Spinal Cord Injury**

Abstract

Purpose: Functional electrical stimulation (FES) can be effective in assisting physical and psychosocial difficulties experienced by people with spinal cord injury. Perceived benefits and barriers of the current and future use of FES within the wider spinal cord injury community is currently unknown. The main objective of this research was to explore the spinal cord injury community's views of the use of FES to decrease disability in rehabilitation programmes.

Materials and methods: An online and paper questionnaire was distributed to people with spinal cord injury, health care professionals and researchers working in spinal cord injury settings in the United Kingdom.

Results: A total of 299 participants completed the survey (152 people with spinal cord injury, 141 health care professionals and 6 researchers). Common views between groups identified were: (1) FES can be beneficial in improving physical and psychosocial aspects and that (2) adequate support and training for FES application was provided to users. Barriers to FES use included a lack of staff time and training, financial cost and availability of the equipment. Sixty three percent of non-users felt they would use FES in the future if they had the opportunity.

Conclusions: Users' views were important in identifying that FES application can be beneficial for people with spinal cord injury but also has some resourceful barriers . In order to increase use, future research should focus on reducing the cost of FES clinical service and also address implementation of awareness and training programmes within spinal units and community rehabilitation settings.

Key words: Rehabilitation health technology, Neuromuscular electrical stimulation, users views, awareness, education

Introduction

Each year, between 250,000 and 500,000 people world-wide are paralysed from a spinal cord injury (SCI), with an age- and sex-adjusted rate of three per 100,000 per year in the UK [1, 2]. After the injury, people with both complete and incomplete spinal cord injuries and their carers face a wide range of physical and psychosocial difficulties [3-5]. Various assistive technologies have been used to improve such difficulties in spinal units and in the community. One of these technologies, designed to improve living with these difficulties, is the use of functional electrical stimulation (FES) however, there are benefits and barriers to the use of FES use in the SCI population [6]. This study sought to determine the reasons behind this.

FES is the application of electrical current to excitable tissue to activate paralysed muscles [7]. FES is used in spinal cord rehabilitation settings to maintain or increase range of motion, reduce muscle spasm and the effect of spasticity, prevent atrophy, facilitate movement, ambulation and activities [8, 9]. Long-term use and carry-over effects of FES could result in improved muscle bulk in patients with incomplete spinal cord injuries [10, 11]. Moreover, FES use has an impact on psychological benefits for people with SCI, such as, the feeling of being active during a time when many factors are out of their control [6, 12].

The primary of focus of FES research within SCI appears to have predominantly focused on the effect on the limitations in body structure and function such as to increasing muscle bulk and bone changes and reducing spasticity[11, 13, 14] . There has been an increase in research exploring activity limitations such as walking performance [15, 16]; however, people with SCI also experience participation restrictions due to reduced functional limitations resulting from the injury [17]. Therefore, taking a holistic approach and exploring both physical and psychosocial issues, such as quality of life is also important. For example, in a large survey conducted in the United States of America, both quadriplegics and paraplegics felt that regaining bowel, bladder, sexual and upper limb function were essential to improving quality of life [18].

Taking a user-centred approach involving the wider stakeholder is fundamental in ensuring that future research on FES and clinical rehabilitations services are fit-for-purpose and meet the needs of individuals that are intended to benefit [19-21]. Compared to other neurological conditions [22], there is only a relatively small body of research that has concentrated on exploring the users' perspective of FES within the SCI community[23, 24]. In a focus group study, FES has been reported as beneficial by people with SCI and health care professionals (HCPs) as it was perceived to improve physical impairments, activities and also everyday quality of life [6, 25]. In addition, barriers such as the lack of resources and staff training were also reported. However, there is currently limited research providing views about FES application from a UK wide SCI stakeholders involved in delivery of FES (including users and nonusers) specifically within the National Health Service (NHS) setting. Therefore, it is now important to explore the extent to which the themes from the aforementioned focus group study were held by the wider SCI population.

This current study aimed to explore the perceived benefits and barriers of the use of FES obtained from previously conducted qualitative research [6] are held within the wider SCI community with the aim of identifying key implications for future research and recommendations for the delivery of rehabilitation within this population. This involved developing a series of questionnaires to explore views regarding the current and future use of FES of people with SCI, HCPs and researchers. The questionnaires were based on key themes identified from qualitative research that involved focus groups cognitive interviewing methods were also used within the developmental process [6, 25].

Materials and Methods

Study Design

We conducted a nation-wide cross-sectional open survey across the UK. Ethical approval was sought from the Faculty of XXX (XXX-ETHICS-2010-007) and the XXX NHS Committee (10-H1107-21).Target Sample

The target convenience sample involved people with SCI, health care professionals and researchers involved in FES research within the field of SCI. This involved people with SCI with both complete and incomplete injuries, paraplegia and tetraplegia with a varying age and time since injury. HCPs and people with SCI were recruited with current, previous, and no experience with FES. Researchers working within the area of FES were also invited to participate. Table 1 outlines the inclusion and exclusion criteria for the three groups.

Questionnaire development and testing

Four questionnaires were developed; for 1) People with SCI, 2) HCPs working clinically, 3) HCPs that also carry out research and for 4) researchers. The development and testing process of the questionnaires used a cognitive interview interviewing approach involving people with complete and incomplete paraplegia and tetraplegia, health care professionals and researcher. Detail about the methodology and results has been presented elsewhere [25]. In summary, cognitive interviews were carried out as a part of the development of three questionnaires using themes emerging from focus groups formed the structure and content of the questionnaires [6] involving question about current use of FES, support for use of FES, benefits and barriers, and future use of functional electrical stimulation were generated and inserted into different sections of the questionnaires. The interviews involved presenting first drafts of questionnaires to the participant and using ‘think aloud’ techniques, where the participant verbalised their thoughts and decisions as they completed the questionnaire. The

data were transcribed and analysed using content analysis. The questionnaires were amended accordingly.

Using closed and open-ended questions, the questionnaires were designed to gather data on the following: 1) General demography and course of disease; 2) Previous or current use of FES; 3) Support for use of FES in SCI; 4) Benefits of FES; 5) Barriers of FES; 6) An additional section for non-users of FES; 7) Future use of FES (Refer to the Appendix). Both paper and electronic versions of the questionnaires were available.

Recruitment and survey administration

Participants were recruited from UK wide using posters and participant information packs. People with SCI were recruited from spinal centres and charities (INSPIRE and ISCoS) and were identified by an external person from the research for example a research manager or nurse. The HCPs were recruited from a research network (UKIFESS) and spinal centres. The researchers were recruited at academic conferences and through specialist groups. Interested participants were provided an information pack included the participant information sheet and a reply slip. Participants either completed the questionnaire online or else sent back the reply slip to the researchers. The respective paper questionnaire with a prepaid envelope was posted to participants and they were asked to return their completed questionnaire with no further identifying information. On the reply slip, participants also had an option to complete the questionnaire via telephone with the researcher filling in the responses on the paper version. The web e-questionnaires were made available on the project website. The link to the individual questionnaires contained an invitation letter, the participant information sheet, and the specific e-questionnaire containing approximately three items per page. Participants were able to review and change their answers on the e-questionnaire through a back button. Through an IP check, a unique user identifier was provided to each participant to avoid duplicate questionnaire entry and to ensure data protection. Consent to participate was gained

at the beginning of the questionnaire and participation was voluntary. Data was collected over a two-year period.

Data analysis

Both data from completed and early-terminated questionnaires were analysed. Using a coding manual, data from the paper questionnaires were inputted on Excel and data from the online versions were downloaded from the program in an Excel format. Descriptive analyses were conducted using statistical software (SPSS vs.21 for windows (IBM Corp, Armonk NY)). Data from the same items of the HCP/Researcher questionnaire were added to the rest of the HCP data. Descriptive statistics including valid percentages were used for analysis of the closed questions. Responses to open-ended questions were analysed by the PI of the research using inductive content analysis, which involved classification and reduction of data into contextual elements and quotes [26].

Results

In total, 299 participants filled in the questionnaire. In total, 152 people with SCI (73% Male, 27% Female) with 60% had a cervical, 37% had a thoracic and 3% had a lumbar SCI. Also, 134 HCPs working clinically (46% physiotherapists, 21% occupational therapists, 17% nurses, 3% doctors), seven HCPs with research experience and six researchers completed the questionnaires (Table 2). In order to provide an in-depth understanding of the key issues, results of both the open and closed-ended questions were merged together for each questionnaire section.

Use and assessment of FES

Of the 145 respondents with SCI who completed this section, 48.2% (n=70) had experience of using FES, and 51.7% (n=75) had no experience of using FES. The majority of the participants (n=69) except one reported experience of using FES externally and only one participant (n=1) had implanted FES. From the HCPs respondents, 73.3% (n=96) were currently using or had previously used FES and 26.7% (n=35) of HCPs never used FES. In the cases where participants had used FES, in 60.9% (n = 39) of the time it had been funded by the NHS (60.9%, n=39) and for 26.6% (n=17) of the time it was privately funded.

Participants with SCI agreed or strongly agreed that they were adequately assessed for FES (76.6%, n=49), were offered FES at the right time (71.4% n=46), given adequate training (72.0%, n=41) and adequate support (77.6%, n=45) and would recommend FES to other People with SCI (84.7%, n=50). However, the open-text data revealed some important themes relating to the provision of information regarding the use of FES showing that people often required further information, had no information, wanted to try FES at an earlier stage or did not have the opportunity at all. For example, *'I would have liked to have known more about FES at an earlier stage'* (People with SCI not using FES).

Important factors that HCPs needed to consider before assessment for FES were highlighted: clinical judgement (62.5%, n=50), experience in application (46.9%, n=38) and patient personal goals (41.8%, n=33). Psychosocial factors that were also considered before trying FES were: patient commitment (63.9%, n=53) and patient expectations (39.0%, n=32). Important factors of discontinue of use were: poor response (57.8%, n=48), skin allergy (50.0%, n=41) and patient's tolerance (43.4%, n=36). HCPs agreed or strongly agreed that they were given adequate training of FES (78.6%, n=66) and they would recommend the use of FES for People with SCI (89.4%, n=76).

Benefits of FES

From both the open and closed-ended questions it was clear that the main benefits for people with SCI of external FES devices were to improve mobility (53.8.0% [n=31] agreeing and 22.4% [n=13] neutral) and muscle strength (54.5% [n=25] agreeing and 23.6% [n=13] sometimes) (Figure 1). From the open question data participants discussed more general mobility improvement from using FES, such as, '*falls and tripping*', '*reducing drop foot*' and '*improving walking*'. For example:

'I have drop foot so the device was used to assist in my right [foot] being lifted whilst walking therefore giving me enhanced mobility'.

'...FES allows me to walk on different terrain, example rough paths, beach, without tripping'

(People with SCI, using FES)

However, with regard to the benefits of FES many indicated they 'did not know' or it 'was not applicable to them', for example, improving arm movements (68.7%, n=35), cardiovascular fitness (54.0%, n=27), reducing pressure sores (73.4%, n=36), improving bladder and bowel function (87.8%, n=43), breathing (88.0%, n=44), coughing (89.8%, n=44) and sports and recreation activities (58.0%, n=29) (Figure 1). On the other hand, for HCPs the main benefits were for arm movements (75.3% [n=61] complete, 81.7% [n=67] incomplete), lower limb movements (51.9% [n=41] complete, 66.7% [n=54] incomplete) and mobility (54.4% [n=43] complete, 66.7% [n=54] incomplete).

Regarding psychosocial benefits, participants with SCI felt that FES resulted in feelings of control (61% [n=36] agreed, 16.9% [n=10] sometimes), sense of independence (59.7% [n=34] agreed, 15.8% [n=9] sometimes) and assisting everyday activities (52.5% [n=31] agreed, 18.6% [n=11] sometimes) (Figure 1). For example, '*Enabling me to remain capable of working - with its financial benefits*' (People with SCI using FES).

HCPs perceived similar beneficial psychosocial impact of FES as being more often beneficial for people with incomplete than incomplete injuries such as: feelings of making progress (67.9% [n=55] complete, 79.1% [n=64] incomplete), sense of independence (55.7% [n=44] complete, 70.9% [n=56] incomplete), engage in social activities (57.0% complete [n=45], 68.8% [n=55] incomplete) and assist in everyday activities (65.0% [n=52] complete, 77.2% [n=61] incomplete) (Figure 1). Barriers of FES

With regard to the barriers for the application of FES in clinical practice, a majority of participants with SCI strongly agreed or agreed that this was due to a lack of staff training (i.e. 57.4%, n=31) and half felt that lack of clinical time was a key issue (i.e. 51.0%, n=27) (Figure 2).

'Not given no aftercare and information as to what might happen after and what it might cause' (person with SCI, using FES)

'...your lucky to get 30mins and they hand you your coat' (person with SCI, using FES)

There was agreement in the responses provided by HCPs with people with SCI that the main barriers for the non-use of FES application is due the lack of training for clinicians (75.3%, n=58).

Participants with SCI also agreed that FES was not used because of the financial cost to the user (51.0% [n=26] agreed, 17.6% (n=9) did not know), lack of availability (56.9% [n=29] agreed, 19.6% [n=10] did not know), needed too much effort (34.6% (n=18) agreed, 23.1% (n=12) did not know) and sensation being too unpleasant (27.4% n=14 agreed, 15.7% n=8 did not know). However, disagreed that it was because of the reliability of the equipment (45.1% [n=23]) or did not know 21.6% [n=11]. Similar to People with SCI, HCPs strongly disagreed or disagreed that the reliability and maintenance of the equipment (77.8% [n=35] and 61.5%

[n=48] respectively) and lack of research evidence (52.0%, n=40) were barriers to the use of FES (Figure 2).

Non-use of FES by people with SCI and HCPs

The majority of people with SCI thought that FES should be part of SCI rehabilitation (54.8%, n=40); however, a large number of 38.4% (n=28) did not know whether it should be part of their rehabilitation (Table 3). HCPs non-users stated that FES is used by 54.8% (n=17) of their colleagues in clinical practice, 29.0% (n=9) did not know and 16.1% (n=5) stated that it was not used. The majority stated that they did not have the opportunity to attend FES training (80.6%, n=25), thought that FES should be part of SCI rehabilitation (67.7%, n=21) and would like use FES in the future (64.7%, n=22). The majority of people with SCI would have liked to use FES in the future (62.9%, n=44), 28.6% (n=20) did not know and 8.6% (n=6) did not wish to use it.

FES research in SCI

HCPs involved in research and researchers agreed (84.6%, n=11) that it was important to obtain users' views for research about FES in SCI. They selected that they often/sometimes involve users in research (81.9%, n=11). Users' views were obtained using focus groups (40.0%, n=10), interviews (30.0%, n=10), informal contact (10.0%, n=10), advisory group (10.0%, n=10) and questionnaires (10.0%, n=10). The majority stated that in the future, they would use focus groups (55.6%, n=9) to obtain users' views. The participants disagreed that obtaining views takes too much time (81.8%, n=11); however, 45.5% (n=11) thought that it slowed down the research process. Views about the future use of FES by people with SCI and HCPs

People with SCI and HCPs agreed or strongly agreed that for FES to be used in the future (Table 4). The strongest view was on that future research should focus on improving awareness amongst clinicians and patients (PwSCI; 82.4% [n=114] and HCP; 82.4% [n=104]). Issues related to the problems with wires were highlighted in open comments, for example:

‘A smaller less obvious and wireless FES would be great as then I could wear skinny jeans, a skirt etc and still use the FES device’ (person with SCI not using FES)

Discussion

As far as the authors are aware, this is the first nationwide survey study exploring the views of people with SCI and HCPs about the current and future use of FES from the SCI community. In this study we used a user-centred approach involving the wider stakeholder has shown to be essential for that future research on FES and the implementation of health technology in clinical services[19, 21, 27]. In summary, the results show that FES was mainly used to improve physical impairments, such as, arm and lower limb movements and muscle strength, mobility and activities of daily living. HCPs and people with SCI agreed that the main barriers of FES provision were lack of training, lack of staff time and funding and financial cost to the user. In order for FES to be used in the future, participants suggested that there should efficient training for HCPs and increased public awareness among clinicians and patients.

Benefits of FES in SCI

In agreement with previously published research, both people with SCI and HCPs agreed that FES lead to physical improvements [9]. This supports work stroke rehabilitation where health care professionals have expressed a need to increase their use of FES with their patients [22].. As identified in previous qualitative research [6], people with SCI felt that FES had a positive effect for them in that it increased their sense of independence and feeling in control. Positive expectations from the benefits of FES could increase a patient's motivation and serve as a coping mechanism to adjust to their condition [28, 29]. Yet, managing recovery expectations has also been identified as a major challenge in the physical rehabilitation of people with SCI [30]. A mismatch could occur between perceived and observed benefits experienced by people with SCI with inadequate measures to explore both physical and psychosocial changes after FES applications [31]. This enhances the point that choosing appropriate measures from body, activity and also participation level from the International Classification of Functioning Disability and Health could help in setting realistic goals and expectations for people with SCI. .

Barriers and future goals for FES research

People with SCI and HCPs agreed that the main barriers of FES provision were lack of training, lack of staff time and funding and financial cost to the user. These issues have also been reported in research exploring the use and implementation of assistive technologies[33], including FES for people multiple sclerosis and stroke [34, 35]. In addition, in order to reach long-lasting effects, FES treatment needs to be included in a rehabilitation programme lasting months and sometimes years [11]. In the UK, commissioners mainly base the amount of funding provided for equipment and training on evidence and demonstration of cost-effectiveness. However, large randomised controlled trials exploring the benefits of FES in SCI on participation or cost-effectiveness are limited.

Exploring ways in reducing the cost and improving awareness should be the next future goals for FES research. The importance of education about FES in SCI and other neurological conditions has been outlined in a recent qualitative study involving interviews by clinicians, engineers and researchers in a recent qualitative study exploring stakeholder perceptions of FES technology [23]. Improving awareness and education about the application of FES should commence at Bachelor level when students are training to become therapists, nurses or doctors. Also, through implementation programmes of FES awareness, researchers could provide recent evidence about FES application to patients, caregivers and healthcare providers [36]. Therefore, this could eventually increase the efficient and effective use of FES in SCI settings.

Study Limitations

This research is not without limitations and therefore the results should be interpreted with caution. Views of people with SCI, HCPs from various disciplines and researchers were obtained, however, the research still lacks the views from caregivers of people with SCI. We believe that we have a good representation of the sample of SCI[37], however there were more respondents with a physiotherapy than occupational therapy or nursing or medical background. Additionally, this research was only conducted in the UK and therefore, certain factors such as the assessment procedure of FES application would vary at an international level. The opinions of FES users may also be influenced to an unknown extent by the information they have received from professionals. Moreover, a prescription for, or recommended use of durable medical equipment might automatically lead the user to believe that its use is both important and effective. Due to the small numbers of participants answering some items, it was decided not to segregate opinions based upon either the equipment or its purpose. Therefore, some views were based upon which equipment the user has been prescribed. The extent to which these beliefs ultimately shape the patient-users'

responses cannot be known from this research. In fact, although this research included a comprehensive sample, we were unable to obtain the same amount of users versus non-users in the HCP population. We also need to consider that the results may not be applicable to countries where private insurance would cover the FES costs. In general we added open questions where more information was needed however we needed to limit the number of open questions to ensure that the questionnaire do not take a very long time to complete. Also, some of questions had a high number of respondents answering to 'I don't know'. This could have impacted the low number of responses to some of the questions. Finally, we were also unable to calculate the response rate since we did not have record the number of questionnaires sent and received.

In spite of these limitations, this is the first survey exploring views of FES in SCI and we believe that this research provides significant information to the area and the results of this study have shown that understanding and implementing users' views could enhance the procedure for health-technology and service development. This research has shown that people with SCI and HCPs agreed that FES can be beneficial for physical improvements. People with SCI and HCPs agreed that the main barriers of FES provision were lack of training, lack of staff time and funding and financial cost to the user. Future research should focus on reducing the cost, efficient training of HCPs and increase public awareness among clinicians and patients.

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Declaration of interest

No potential conflict of interest was reported by the authors.

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Appendix- Questionnaire items

1. SCI questionnaire

Section	Item
1. Background information	<ul style="list-style-type: none"> a. Age b. Gender c. Which country are you from? d. For how long have you had the Spinal Cord Injury (SCI)? e. At what level is your spinal injury? f. Type of injury: A complete injury with tetraplegia; A complete injury with paraplegia; An incomplete injury with tetraplegia; An incomplete injury with paraplegia g. What was the cause of your injury?: An accident; A progressive disease/condition; A non-progressive disease/ condition h. Which is your current primary (main) mobility aid?: I do not normally use a mobility aid; Self-propelled wheelchair; Power Chair; Crutches; Walking Frame; Two walking sticks; One Walking stick; Other i. Do you use any other (complimentary) mobility aids?: Yes; No j. What is your secondary mobility aid? (same as h) k. Can you tell us about your living arrangements?: I live with someone; I live on my own l. Do you have additional help at home?: Yes; No m. Which of the following describes best the additional help you receive?: 24 hour care; Several times during the day; Once a day; Several times a week; Once a week; Less than once a week; Other n. What experience have you had using Functional Electrical Stimulation (FES)?: I have never used FES; I have used FES before, but not now; I am currently using FES o. Please briefly describe below the FES application/s you have used or currently using [open question]
2. Your previous or current use of FES	<ul style="list-style-type: none"> a. What type of FES devices have you used or are you currently using? Implanted Device; External Device; Both b. What do you use or have used FES for?: Improving arm movements; Improving activities of daily living; Improving mobility; Improving muscle strength; Improving cardiovascular fitness; Reduction of spasticity; Prevention of pressure sores; Improving of bladder and bowel function; Improving sexual function; Breathing assistance; Assisted cough; Sport and Recreation; Other: c. Are you currently using FES?: Yes; No d. If you are not currently using FES, how frequently did you use it in the past?: All day most days; A short time most days; At least once a week; At least once a month; Whenever I need it; Other

	<p>e. Please feel free to add more details on your use of FES [open question]</p> <p>f. How frequently are you using FES now? (same as d)</p>
3. Support for use of FES in SCI	<p>a. Who suggested the use of FES in your rehabilitation (management) programme?: I suggested it; The therapist; A family member or carer; The doctor; Another person with SCI; A representative from a private company; don't know; Other:</p> <p>b. How is your FES treatment funded?: Privately; National Health Service; Insurance; Compensation Package; Research Funding; Charity; Non-Governmental Organisation; Other</p> <p>c. After it was decided that FES would be used for you, how long did you have to wait to start using it?: No waiting time; Within a week; Between 1-4 ; Over a month; Over 6 months; More than a year; I don't know; Other</p> <p>d. Could you please provide more detail why you had to wait over a month before using FES [open question]</p> <p>e. In my view: (Likert scale: Strongly agree to strongly disagree)</p> <p>I was adequately assessed (briefed) before I was prescribed FES.</p> <p>I was offered FES at the right time of my rehabilitation process</p> <p>I was given adequate training on the use of FES</p> <p>I was given adequate support to using FES</p> <p>I would recommend the use of FES to other people with SCI</p> <p>Please include any comments relating to this section [open question]</p>
4. Benefits of FES	<p>In my experience FES can improve: (Likert scale Never-Always)</p> <p>Arm movement; Leg movement; Mobility; Muscle strength; Cardiovascular fitness; Prevention of pressure sores; Bladder and bowel function; Breathing; Coughing; Sport and recreation; Other:</p> <p>In my view FES can help:</p> <p>Make you feel you are making progress; Give a sense of control; Create a sense of independence; Participation in social activities; With everyday activities</p> <p>Other</p> <p>Please include any comments relating to this section [open question]</p>
5. Reasons why FES is not used	<p>In my view FES may not be used because of (Likert scale Strongly agree to Strongly disagree):</p> <p>Lack of clinicians' training in using FES; Lack of training for people with SCI; Lack of clinicians' understanding and awareness of patients' hopes and expectations; Staff time; My own lack of time; A lack of research evidence; A lack of evidence in clinical practice; Of lack of knowledge about who</p>

	<p>will benefit; It can take too much effort; Clinicians are unsure whether it will work for people with SCI; The sensation being too unpleasant; Its ineffectiveness in restoring sensation; The financial cost to the user; A lack of availability of FES; Maintenance of the equipment; Reliability of the equipment; The anxiety about a surgical procedure</p> <p>Please include any comments relating to this section [open question]</p>
<p>6. Understanding of FES (For non-users)</p>	<p>a. Was FES ever offered to you?: Yes; No; I don't know</p> <p>b. Do you feel that FES should be part of the rehabilitation and management programme of people with SCI?: Yes; No; I don't know</p> <p>c. I have not used FES because (Likert scale Strongly disagree to Strongly Agree): I do not think it is effective; I feel it may be too much of an effort; It may lead to additional complications; Implanted systems involve invasive surgical procedures; I feel I do not have the time to use FES; It might give unrealistic hope</p> <p>d. If you had the opportunity; would you like to use FES in the future?: Yes; No; I don't know</p> <p>e. If you had the opportunity; what type of FES would you like to use?: External; Implanted; I don't know</p>
<p>7. Future use of FES</p>	<p>f. With regard to all FES devices, I feel that further research and development needs to be carried out on (Likert scale Strongly disagree to Strongly agree): Making FES equipment easier for the patient to use Making the FES equipment easier for the clinician to use To establish research evidence for its effectiveness Overcoming the problems of electrode placement How FES users would like FES to look (cosmetic appearance) Reducing the size of FES devices Making implanted devices that require less invasive surgery Making the equipment wireless Improving sensation with FES Reducing the cost of providing FES Improving awareness among clinicians and patients Better support and training for clinicians Better support and training for people with SCI Agreed guidelines for using FES Developing better community services</p> <p>Please include any comments relating to this section [open question]</p>

2. HCP Questionnaire

Section	Item
1. Background information	<ul style="list-style-type: none"> a. Profession and job title b. The country in which you work c. For how long have you have you worked with people with Spinal Cord Injuries (SCI)? d. Have you ever used FES with people with SCI?: Never; In past not currently; Currently e. How experienced are you in using FES with people with SCI?: Inexperienced; Quite experienced; Very experienced f. Please briefly describe below the FES applications you have experience of [open question]
2. Your previous or current use of FES	<ul style="list-style-type: none"> g. What type of FES devices have you used or are you currently using? Implanted Device; External Device; Both h. What do you use or have used FES for?: Improving arm movements; Improving activities of daily living; Improving mobility; Improving muscle strength; Improving cardiovascular fitness; Reduction of spasticity; Prevention of pressure sores; Improving of bladder and bowel function; Improving sexual function; Breathing assistance; Assisted cough; Sport and Recreation; Other:
3. Support for use of FES in SCI	<ul style="list-style-type: none"> a. Who usually initiates the use of FES in the rehabilitation (management) programme? The patient; The therapist; A family member or carer; The doctor; Another person with SCI; A representative from a private company; don't know; Other: b. How is your FES treatment funded?: Privately; National Health Service; Insurance; Compensation Package; Research Funding; Charity; Non-Governmental Organisation; Other c. What factors do you think are important in the decision to use FES?: Your experience in the application proposed; Clinical judgement of potential success; Staff time; Resources; Patients' personal goals; Funding; I don't know; Other d. What factors do you think are important in the decision to discontinue using FES?: The presence of skin allergy; Patient's tolerance to pain or discomfort; Lack of funding; Poor compliance; Poor response; I don't know; Other: e. Which of the following psychological and sociological factors do you think are important in the decision to use FES? Please rank from 1-6 where 1 is the most important and 6 is the least important: The patient's commitment The patient's level of understanding Available support from members of staff Available support from family members or carers The patient's expectations

	<p>The patient's financial situation I don't know Other</p> <p>f. After a decision has been made to use FES, on average how long do people with SCI have to wait before using it?: No waiting time; Within a week; Between 1-4 ; Over a month; Over 6 months; More than a year; I don't know; Other</p> <p>g. In my view: (Likert scale: Strongly agree to strongly disagree) People with SCI are adequately assessed for their suitability before being prescribed FES FES is usually offered at the right time of the rehabilitation process People with SCI are not informed about FES at the right time in the rehabilitation process I was given adequate training in using FES I would recommend the use of FES to people with SCI If you answered 'disagree' or 'strongly disagree to question 3k please comment below: [open question]</p>
<p>h. Benefits of FES</p>	<p>In my experience FES can improve: (Likert scale Never-Always) Arm movement; Leg movement; Mobility; Muscle strength; Cardiovascular fitness; Prevention of pressure sores; Bladder and bowel function; Breathing; Coughing; Sport and recreation; Other:</p> <p>In my view FES can help: Make you feel you are making progress; Give a sense of control; Create a sense of independence; Participation in social activities; With everyday activities Other</p> <p>Please include any comments relating to this section [open question]</p>
<p>i. Reasons why FES is not used</p>	<p>In my view FES may not be used because of (Likert scale Strongly agree to Strongly disagree): Lack of clinicians' training in using FES; Lack of training for people with SCI; Lack of clinicians' understanding and awareness of patients' hopes and expectations; Staff time; My own lack of time; A lack of research evidence; A lack of evidence in clinical practice; Of lack of knowledge about who will benefit; It can take too much effort; Clinicians are unsure whether it will work for people with SCI; The sensation being too unpleasant; Its ineffectiveness in restoring sensation; The financial cost to the user; A lack of availability of FES; Maintenance of the equipment; Reliability of the equipment; The anxiety about a surgical procedure</p> <p>Please include any comments relating to this section [open question]</p>
<p>j. Understanding of FES (For non-users)</p>	<p>a. Is FES used by other staff members in your clinical setting? Yes; No; I don't know</p> <p>b. Have you had the opportunity to attend FES training courses? Yes; No; I don't know</p>

	<p>c. Do you feel that FES should be part of the rehabilitation and management programme of people with SCI?: Yes; No; I don't know</p> <p>d. I have not used FES because (Likert scale Strongly disagree to Strongly Agree): I do not think it is effective; I feel it may be too much of an effort for the patient; It may lead to additional complications; Implanted systems involve invasive surgical procedures; I feel I do not have the time to use FES; It might give unrealistic hope</p> <p>e. If you had the opportunity; would you like to use FES in the future?: Yes; No; I don't know</p> <p>f. If you had the opportunity; what type of FES would you like to use?: External; Implanted; I don't know</p> <p>g. Please include any comments relating to this section [open question]</p>
<p>h. Future use of FES</p>	<p>i. With regard to all FES devices, I feel that further research and development needs to be carried out on (Likert scale Strongly disagree to Strongly agree): Making FES equipment easier for the patient to use Making the FES equipment easier for the clinician to use To establish research evidence for its effectiveness Overcoming the problems of electrode placement How FES users would like FES to look (cosmetic appearance) Reducing the size of FES devices Making implanted devices that require less invasive surgery Making the equipment wireless Improving sensation with FES Reducing the cost of providing FES Improving awareness among clinicians and patients Better support and training for clinicians Better support and training for people with SCI Agreed guidelines for using FES Developing better community services</p> <p>Please include any comments relating to this section [open question]</p>

Tables

Table 1: Inclusion and exclusion criteria of people with spinal cord injury, healthcare professionals and researchers

Group	Inclusion Criteria	Exclusion Criteria
People with a SCI	<ul style="list-style-type: none"> • A diagnosed SCI at above the level of T12 as FES is only beneficial to those who have an injury which lies in this range • More than 3 months post-injury • Over 18 years 	<ul style="list-style-type: none"> • Unable to understand the consent procedures and questionnaire items as translation costs were not available
Healthcare professionals	<ul style="list-style-type: none"> • Currently working professionally with People with SCI • Either qualified clinical staff (e.g. Allied healthcare, nurses, consultants, psychologists etc.) or healthcare assistants (e.g. healthcare works, rehabilitation assistants etc.) 	
Researchers	<ul style="list-style-type: none"> • Currently working or have worked within the field of FES and SCI 	

Table 2: Background information of participants with SCI and health care professionals

Item	N (%)
	Participants with SCI
Gender (M/F)	110 (73.3%) Male 40 (26.7%) Female
Level of Injury	88 (59.9%) Cervical 54 (36.7%) Thoracic 5 (3.4%) Lumbar
Cause of Injury	107 (71.3%) Accident 14 (9.3%) Progressive 18 (12.0%) Non-progressive 11 (7.3%) Other
Primary mobility aid	9 (6.0%) No use of aid: 81 (54.4%) Self-propelled wheel-chair 29 (19.5%) power-chair 20 (13.5%) One/two walking sticks 4 (2.7%) Crutches 1 (0.7%) Walking frame 5 (3.4%) Other
	Health care professionals
Profession	62 (46.3%) Physiotherapists 44 (20.6%) Occupational Therapists 22 (16.8%) Nurses 5 (3.8%) Doctor 15 (11.1%) Other
Mean (SD) months working with people with SCI	128.5 (104.0)

Table 3: Responses of statements about non-use of FES by People with SCI and HCPs

	People with SCI			HCPs		
	Agree	Disagree or strongly disagree	Don't know	Agree	Disagree or strongly disagree	Don't know
FES not used because it is:						
Ineffective	5.9% (n=4)	25.0% (n=17)	55.9% (n=38)	0% (n=0)	63.6% (n=21)	27.3% (n=9)
A lot of effort by user	4.4% (n=3)	32.3% (n=22)	52.9% (n=36)	3.0% (n=1)	63.6% (n=21)	27.3% (n=9)
Leads to complications	8.6% (n=6)	24.6% (n=17)	55.1% (n=38)	3.0% (n=1)	36.4% (n=12)	42.4% (n=14)
Implanted systems are invasive	12.0% (n=8)	26.8% (n=18)	52.2% (n=35)	24.2% (n=8)	21.2% (n=7)	30.3% (n=10)
No time	4.4% (n=3)	45.6% (n=31)	41.2% (n=28)	9.1% (n=3)	42.4% (n=14)	27.3% (n=9)
Gives unrealistic hope	5.8% (n=4)	37.7% (n=26)	49.3% (n=34)	9.1% (n=3)	24.3% (n=8)	33.3% (n=11)

Table 4: Issues that need to be explored in future research

Future of Functional Electrical Stimulation	People with spinal cord injury	Health care professionals
Easier to use for the patient	65.0% [n=117]	72.5% [n=109]
Easier to use for the clinician	50.9% [n=116]	55.0% [n=109]
Evidence for its effectiveness	68.6% [n=118]	81.6% [n=109]
Cost	73.2% [n=112]	78.9% [n=109]
Awareness among clinicians and patients	82.4% [n=114]	82.4% [n=104]
Research agreed guidelines	63.5% [n=115]	82.7% [n=110]
Overcome problems with electrode placement	59.3% [n=118]	81.2% [n=102]
Making FES wireless	65.5% [n=116]	75.2% [n=94]
Research involving larger trials	N/A	73.7% [n=110]

Figures

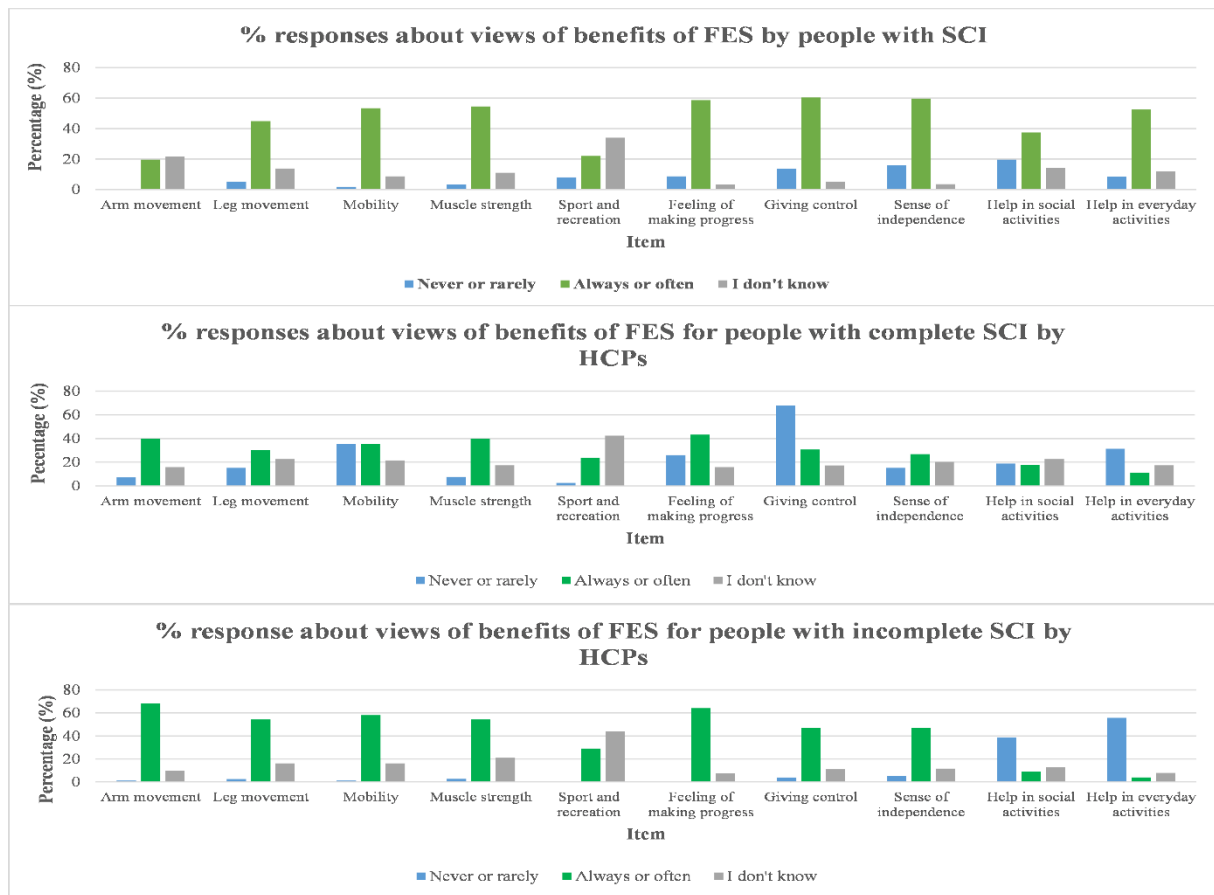


Figure 1: Bar charts showing the different views about the benefits of FES by people with SCI [top figure] and health care professionals about complete and incomplete SCI [bottom two figures]

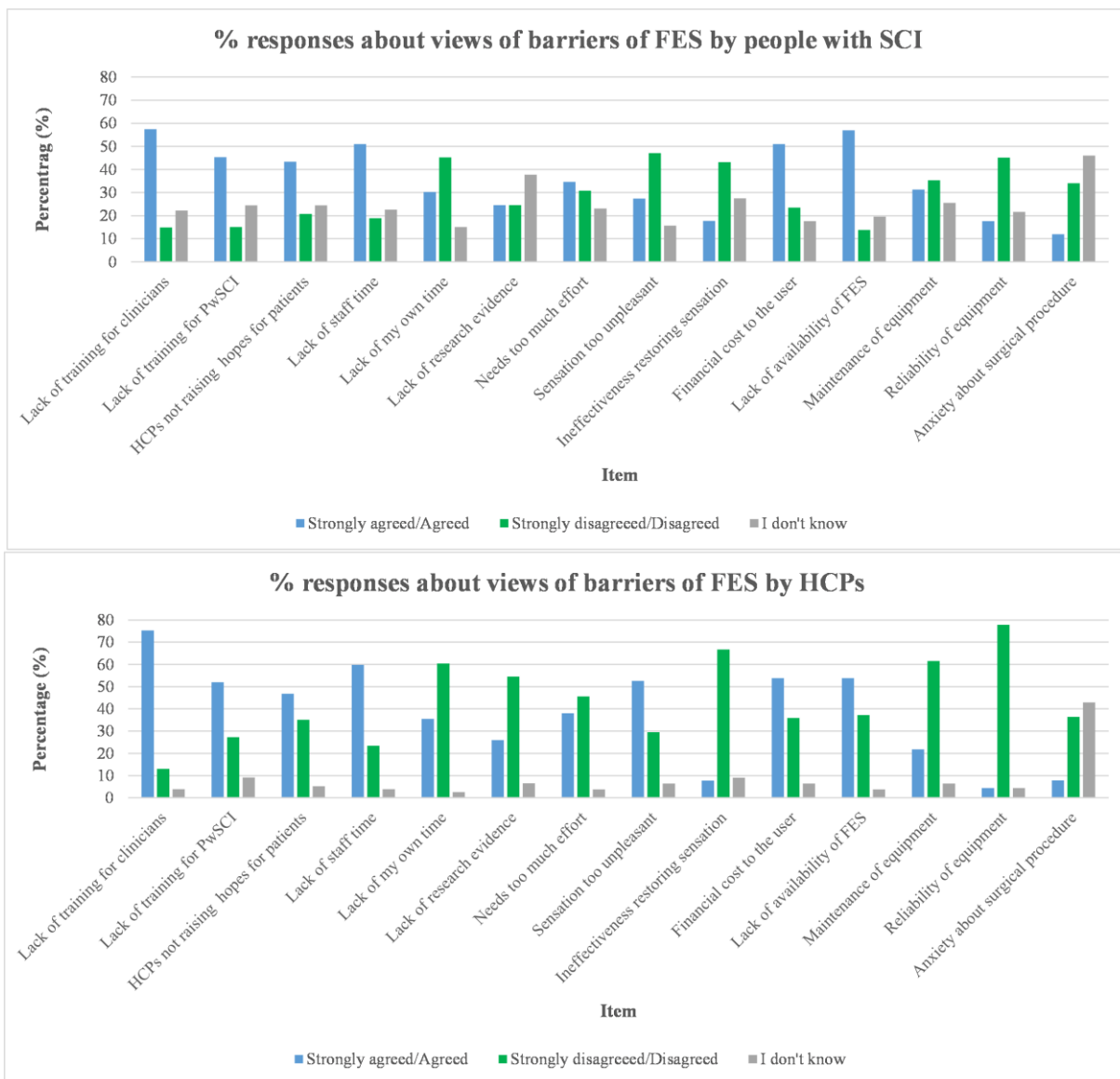


Figure 2: Two bar charts showing the different views about the barriers of FES by people with SCI [top] and HCPs [bottom]

Figure Legends

Figure 24: Bar charts showing the different views about the benefits of FES by people with SCI [top figure] and health care professionals about complete and incomplete SCI [bottom two figures]

Figure 2: Two bar charts showing the different views about the barriers of FES by people with SCI [top] and HCPs [bottom]