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**‘Cognitive interviewing techniques: applied in the development of a questionnaire on Functional Electrical Stimulation in Spinal Cord Injury study’**

**Category: Research**

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## Abstract

### **Aim**

The aim of this paper is to illustrate the application of a technique, Cognitive interviewing, which was used in the development of three questionnaires to determine the views of use of Functional Electrical Stimulation (FES) by people with Spinal Cord Injury (SCI), Health Care Professionals (HCP) and researchers working in SCI.

### **Methods**

Three questionnaires for the three populations were developed in order to explore views about the current and future use of FES. The questionnaires were reviewed and discussed by the team. Cognitive interviews were carried out at participants' homes, university or workplace and each interview lasted a mean time of 65 minutes. The interviewer used 'think aloud' techniques. They were transcribed and analysed using content analysis.

### **Findings**

Twelve participants (four people with SCI, four HCPs and four researchers) from across United Kingdom took part. The process identified several areas for modification, including clarification of words, format and legibility of questions, changes to sections, and the layout of the questionnaires.

## **Conclusions**

Cognitive interviewing ensured that the questionnaires were readable, clear and relevant, unambiguous and related to current clinical practice and research. The technique resulted in good quality questionnaires with enhanced patient-centred language.

Key Words: questionnaire development, functional electrical stimulation, spinal cord injury, rehabilitation, users' views

## Main Manuscript

### **Introduction**

Spinal Cord Injury (SCI) is a catastrophic injury to the neurological system resulting in permanent and non-permanent neurological deficits (Hamid and Hayek, 2008). People with Spinal Cord Injury (SCI) experience physical limitations which affects dailies of activity living and level of participation. Rehabilitation interventions focus on physical limitations, improve activity level, and promote ambulatory function for people with SCI (Bailey et al., 2010). Functional Electrical Stimulation (FES) is a rehabilitation health technology commonly used as an assistive technology which stimulates paralysed muscles by depolarization of the intact peripheral nerve (Hamid and Hayek, 2008). Pulsed electrical currents are transmitted by electrodes on the skin or implanted close to a peripheral nerve or nerve root (Creasey et al., 2004). For patients with SCI, interventions have been developed to support and restore function and movement. In addition, specific attention has also been attributed to application of FES as a respiratory-assist device, a hand-grasp system, and aid standing and walking, bowel and sexual function and bladder control (Gorman, 2000). Therefore, FES can potentially improve quality of life and overall physical ability of people with SCI (Hicks et al., 2011, Dolbow et al., 2013). However further research is required exploring the current and future use of FES in SCI. This paper illustrates an example of cognitive interviewing in the development of three questionnaires exploring use of FES in SCI rehabilitation. Data are presented to support the description of a successful application of the technique.

Cognitive interviewing is a technique used in questionnaire development and is considered a useful method of identifying and correcting problems with questionnaires (Beatty and Willis, 2007). Cognitive interviewing was developed in the 1980's by survey methodologists and psychologists. It involves sitting with respondents as they are completing the questionnaire and gaining verbal information from the respondent to determine whether the question is producing the information that the researcher intended to achieve (Beatty and Willis, 2007). Within the questionnaire development process simply piloting the questionnaires with a sample of the target population is not seen as comprehensive enough to identify problems with the wording and understanding of the questions (Carbone et al., 2002).

Two approaches are usually used in cognitive interviewing and these are 'think-aloud' and 'probing' (Beatty and Willis, 2007). The 'think aloud' approach can be used i) concurrently, for example while the questionnaire is being answered or ii) retrospectively once the questionnaire or section is completed. A 'probing' approach involves the researcher asking questions to prompt and obtain an idea about the cognitive processes being used when responding to the questionnaire (Willis, 1994, Beatty and Willis, 2007, Murtagh et al., 2007). By presenting the questions to the target population any thoughts and ideas are stimulated when reading the question as well as checking the clarity of the wording. This can enhance the questionnaire's reliability and validity (Carbone et al., 2002, Knafl et al., 2007, DeVellis, 2011). It has become increasingly popular over the past 20 years, and has been used in the development of health related questionnaires, such as, national nutrition surveys and in illness

populations, such as, with people with cancer and asthma (Grant et al., 1999; Subar et al., 1995, Wu and McSweeney, 2004, Murtagh et al., 2007).

Questionnaires have been developed exploring the use of assistive technologies including FES in stroke (Hughes et al., 2013). However, this is the first research integrating the cognitive interviewing methodology in questionnaire development for SCI settings. In spite of the various applications of FES in SCI, only a small percentage of people with SCI who might benefit from FES currently use it (Tator, 2006, Meadows, 2008). This may be because FES is not as effective in practice as small clinical research studies have suggested, devices are not acceptable to users (people with SCI and Health Care Professionals [HCPs]) or due to lack of effective translational research following the development of FES technologies (Brown-Triolo et al., 2002). Lack of funding and support for technologies in health care settings may be a critical factor (Donovan-Hall et al., 2011), however, there appears to be a lack of understanding of the key issues that impact on the translation to clinical practice and this highlights the importance of understanding the end users' views and perspectives. The questionnaires discussed in this paper are part of a larger programme of research that aims to explore the perceived benefits and barriers to the use of FES within the SCI community. The first stage of the present research was a large qualitative study exploring views regarding current and future use of FES by people with SCI, HCPs and researchers (Donovan-Hall et al., 2011). In the aforementioned study, the main themes identified were: the decision to use FES in SCI rehabilitation; physical improvements; doing something active; lack of resources; and future use. The main benefits of FES extended

beyond conventional measures of efficacy and cost-effectiveness and included subtle effects on wellbeing and participation. Moreover, the key barriers identified were the lack of knowledge of the effectiveness of FES, and when and where FES should be used. In order to explore the extent to which the views from the qualitative study were held by the wider SCI community, the themes were used to develop a series of questionnaires (Donovan-Hall et al., 2011). This article describes the process of development of the questionnaires, using cognitive interviews with people with SCI, clinicians and researchers.

## **Method**

### *Participants*

Using purposive sampling, two participants were selected from the wider pool of participants who took part in the previous focus group study, four from specialist interest groups and six from research conference (Donovan-Hall et al., 2011). These were a) people with complete and incomplete paraplegia and tetraplegia and a varying age and time since injury, b) HCPs and c) researchers.

People with SCI and HCPs in the wider study were recruited with current, previous, and no experience with FES. The participants were approached via face-to-face or telephone meetings. An invitation pack containing an invitation letter, a participant information sheet and a prepaid envelope was given to each potential participant by the authors of this paper (LTT and MDH).



## *Methodology*

We used a pragmatic (Cherryholmes, 1992) realist approach where we were interested in people's views of how they saw the questionnaires. Cognitive interviews were carried out as a part of the development of three questionnaires. This section presented the initial phase of the questionnaire formation and development followed by the methodology of the cognitive interviews.

### Questionnaire development prior to cognitive interviewing

Themes emerging from focus groups formed the structure and content of the questionnaires (Donovan-Hall et al., 2011). Items in relation to the current use of FES, support for use of FES, benefits and barriers of FES and future use of FES were generated and inserted into different sections of the questionnaires, which were different for each of the three questionnaires (see figure 1).

Each section comprised 5 to 20 items using open and closed questions. The total number of items for the questionnaire at this point was 55. When designing the questionnaire we had taken into account *structure*, a) similar sections in the three questionnaires, b) more general to more specific questions c) demographic information at the start, d) 43-45 closed questions to allow focus and 8-10 open questions to allow people to add comments and also *wording* with the aim of avoiding jargon, ambiguous questions; asking two aspects in one question, and using leading questions (Del Greco and Walop, 1987).

## Cognitive Interviews

All interviews were conducted by LTT either at the participant's home or place of work between April and September 2010. The author was not known by the participants before the research. Ethical approval was given by the Faculty of Health Sciences Research Ethics Committee of the University of Southampton (SoHS-ETHICS-2010-007).

Prior to the interview, the purpose and process of cognitive interviewing was explained to the participants and any questions were answered. Informed consent was then obtained. During the interview the participant sat in front of the interviewer and was shown, for the first time, the relevant questionnaire. During the interview, mainly 'thinking aloud' techniques were used (Willis, 2004). The advantage of the 'thinking aloud' process was that it reduced the chance that the interviewer introduced bias into data collection process and in order not to disturb the thinking process of the participants only a few probes were used per interview (Oksenberg et al. 1991). The participant was asked to read each question aloud and answered by verbalising his/her thoughts about the question. When a participant found it difficult to express his/her thoughts the interviewer supported them by saying for example: "what did you mean when you said I do not understand this question?". Each participant gave his or her interpretation of the question and then suggested changes to the wording and structure. No problems were encountered during the methodological process. The interviewer took brief notes about the responses during the interview and these were retained by the

researcher and stored securely. The mean time of interview was 65 (range between 45-90 minutes) and recorded on audiotape.

### *Data Analysis*

Audio recordings were transcribed verbatim and pseudonyms/numbers were allocated to each participant and all identifiable information of the participants was removed to maintain anonymity. The field notes were used when some recordings were unclear during transcription. The transcripts were analysed using inductive content analysis (Weber, 1990; Elo and Kyngas 2008) which involved classification and reduction of data into contextual parts of meaningful data (Hsieh and Shannon, 2005). The data was reviewed independently by LTT and MDH. This process identified recurring codes for modifications or deletions per item by going through the transcript line by line. During consensus meetings, codes were compared and agreed codes were added to summary tables per section (an example of a summary table is found in the Appendix). For each code, participants' interpretations were then compared by the two researchers and items were added, modified or deleted when two or more participants made similar suggestions. Once agreement was achieved between researchers, the questionnaires were then modified and presented to the research team at a planned meeting at the University of Southampton and participants via email for final comments. Minor modifications were then carried out. Due to categorical saturation and the team decided that the questionnaires were at an optimal level for the piloting stage.

## **Findings**

Twelve participants (seven (67%) male and five (33%) female) were interviewed; four people with SCI, four HCPs and four researchers. Of the twelve participants, eight (75%) had experience using FES and four (25%) did not have experience using FES. Further detail is presented in table 1.

Key changes made to the questionnaires are presented, illustrating how the final versions were developed. Originally each questionnaire comprised 55 items but increased to 75 items (65 open and 10 closed). The following sections describe how items were retained revised or deleted, for every section of the questionnaires.

### *Section one-background information*

For the SCI questionnaire, two participants with SCI suggested that ‘other’ should be added to the ‘cause of the injury’, since participants will have different causes. In addition, two participants felt that the question about the ‘additional help’ that they were receiving should have detailed items from ‘once a day’ to ‘24 hour care’ and ‘several times during the day’, and comment boxes should be larger to allow more writing space. All HCPs and researchers felt that general questions about their age and gender should be retained; however, it was suggested that more space in the questionnaire should be provided for open questions such as for job title. In addition, two researchers suggested that the option of selecting ‘both’ should be available for the item about the experience of the type of FES.

### *Section two- previous use of FES*

For this section, questions were asked about the type and application of FES in rehabilitation. Two participants with SCI suggested the term ‘upper limb’ be changed to ‘arm’ and an additional item should be added about use of FES for coughing. Two participants with SCI suggested that questions such as ‘how frequently did/do you use your FES device?’ should include more options such as ‘once a week’ and ‘whenever I need it’. One HCP and one researcher felt that the word ‘user’ needed to be explained, therefore, the definition of ‘user’ was explained in the instructions at the top of the section. One of the items exploring the rehabilitation process for activities of daily living of people with SCI, was declared as a ‘sweeping question’ by all the researchers and therefore deleted.

### *Section three- views about the decision process for use FES*

In this section, questions were asked about who and how the decision was made about the use of FES. All researchers felt that they did not have enough experience to answer some of the questions related to the topic. It was therefore suggested that adding in an ‘I don’t know’ option in the questions asked about the decision to use FES in the rehabilitation process. The HCPs did not suggest any changes. Two participants with SCI suggested that in the Likert Scale, ‘neither’ should be changed to ‘undecided’ and words, such as, ‘assessed’ and ‘prescribed’ be changed to ‘informed’.

#### *Section four- views about the benefits of FES in SCI*

In this section, two participants with SCI suggested separating the questions about the physical capabilities and the psychosocial questions into different boxes. Two HCPs suggested that the benefits stated were different for people with complete and incomplete spinal injuries. Therefore, it was decided to split the table into complete and incomplete injuries as defined by Maynard et al., 1997, for each stated benefit. Two researchers also suggested that the ‘strongly disagree to agree’ Likert scale should be changed to a ‘never to always’ scale.

#### *Section five- views about the barriers of FES in SCI*

In this section, two participants with SCI suggested changes in the wording of the statements provided for example: the option ‘neither’ was also changed to ‘undecided’. Two participants with SCI and two HCPs suggested that change of words and statements such as ‘dealt with’ and ‘impacted’ to ‘addressed’ and ‘effected’ and also ‘sensation was intolerable’ to ‘unpleasant’. Two participants per group suggested that the following items: “Limited research showing the benefits of FES is a barrier to its application” and that “Some patients with SCI think the uncertainty about whether FES will work for them, make it not worth trying” were too leading and therefore they were deleted.

#### *Section six- views and understanding of FES*

This section was provided for people without experience of FES. As suggested by two participants with SCI, one item regarding the application of FES was deleted since the

participants did not have enough information about FES and the option of ‘I don’t know’ was also added to four questions of this section.

#### *Section seven- views about the future use of FES*

Two participants with SCI suggested including an item about the extra support of use of FES for people with SCI as a future goal for FES application. Two researchers suggested that a section about the long-term reliability, reducing regulatory barriers and financial support for implanted devices should be added to this section. Three HCPs suggested that better clinical guidelines should be added as an item about the future use of FES.

#### **Discussion**

Cognitive interview techniques improved and refined the questionnaires. The items, layout and scales of the questionnaires were either modified or deleted. It was noted that there was enough content in the questionnaires since hardly any new items were added to the questionnaires. The process was essential in identifying problems in the format of the questionnaires, legibility of items, and comprehension of words and phrases. This process has shown that the study population can encounter difficulties when completing questions relating to topics such as FES. For example, ambiguous instructions before each section were explained in simpler and shorter statements. Similar results in questionnaire design have been found in palliative care research (Murtagh et al., 2007). General indication about the participants’ processing of information and verbalisation of thoughts was crucial for the cognitive interview process (Beatty and Willis, 2007). In

the present study, HCPs indicated that some questions were confusing since people with complete and incomplete SCI are two different groups. Ambiguous questions are common in questionnaires as was identified in questionnaires relating to nutrition (Carbone et al., 2002).

FES and SCI rehabilitation as a research topic itself is a complex one. Obtaining views about the use assistive technologies in neurological rehabilitation such as stroke has been previously obtained, however specifically focusing on one technology, can be more challenging and specific (Hughes et al., 2013). Applications of FES in SCI differ from those used for other conditions (Sadowsky, 2001). The cognitive interview process was important to appropriately present questions to people with SCI who have no experience of FES. However, increasing awareness of people with SCI about rehabilitation technologies might cause psychological challenges such as raised hopes (Donovan-Hall et al., 2011).

Cognitive interviewing techniques have been used in various health care settings such as palliative medicine (Murtagh et al., 2007). However, the process has never been involved in questionnaire development for people with SCI or assistive technologies. As researchers with clinical experience, we feel that this process is vital for questionnaire development. Cognitive interviews can lengthen the research process but may improve design. As in previous health care research, cognitive interviewing techniques were identified as very beneficial for questionnaire development since it ensured that all participants managed to express their thoughts about the items of the questionnaires (Ahmed et al., 2009). Simply piloting the questionnaires with the sample target



population might not be enough to solve problems with wording of the questions and might reduce the number of respondents of the final questionnaires (Carbone et al., 2002, Cummings et al., 2001). Cognitive interviewing provided information about the questionnaires that would have been impossible to obtain by immediately posting the questionnaires. The benefits of producing better quality questionnaires, full questionnaire completion and more patient-centred language outweigh the costs of time, researcher travel and delay in questionnaire administration for the main study. The main limitation of this research was that all HCPs and researchers had experience working with people with SCI and nearly all had experience using FES. Thus, section six of the questionnaire which focussed for respondents who do not have experience using FES, was only reviewed by one HCP. A larger sample could have given more detailed information about the questionnaires. An additional limitation was that carers of people with SCI were not interviewed, and therefore their views were not accounted for in this research. In addition, only one round of cognitive interviews was carried out. A second round could have identified further modifications to the questionnaires.

The questionnaires have now been developed and were administered to large samples of participants throughout the United Kingdom. The results of this project could potentially inform future research and clinical practice involving FES and also implement guidelines of the use of FES in SCI.

## **Conclusion**

We can conclude that cognitive interviewing is worth the effort and it is an essential part of questionnaire development when exploring complex areas in health and rehabilitation such as FES and SCI. A well-designed questionnaire study is vital for exploring the current and future use of FES in SCI. Questionnaires have been developed for people with SCI, clinicians and researchers exploring such views. The results of the questionnaire study will provide vital knowledge about FES and potentially implement changes to SCI rehabilitation.

## Key Points:

- Cognitive interviewing provides an extra step in questionnaire development
- It is a thorough and worthwhile process involving two approaches: ‘think aloud’ and ‘probing’
- Questionnaires about the current and future use of FES and SCI were developed
- Cognitive interviewing identified areas of modification resulting in clearer and good quality questionnaires
- Cognitive interviewing is thus beneficial for questionnaire development in complex rehabilitation situations

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## Authors Contributions

Dr Lisa Tedesco Triccas-Data collection, data analysis and authorship of journal paper

Dr Maggie Donovan-Hall- Data analysis, and co-authorship of journal paper

Professor Jane Burridge- Data analysis, contribution to critical revision of journal paper

Dr Bridget Dibb- Data analysis, contribution to write-up and final approval of journal paper

Dr Caroline Ellis-Hill- Data analysis, contribution to write-up and final approval of journal paper

Dr David Rushton - Contribution to write-up of journal paper

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### **Statement of Conflicts of Interest**

‘None declared’

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## Tables

**Table 1: Participant characteristics**

Participant Identification Number	Group	Gender	Age Range
P1	SCI	Male	40-50
P2	SCI	Male	70-80
P3	SCI	Male	30-40
P4	SCI	Male	50-60
P5	HCP (Private Physiotherapist)	Female	40-50
P6	HCP (NHS Physiotherapist)	Female	30-40
P7	HCP (NHS Physiotherapist)	Male	50-60
P8	HCP (NHS Occupational Therapist)	Female	40-50
P9	Researcher	Male	50-60
P10	Researcher	Male	30-40
P11	Researcher	Female	40-50
P12	Researcher	Male	30-50

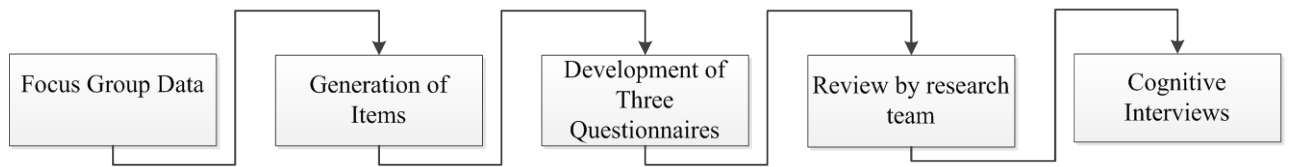
**Appendix Table: An example of a summary table for the section about the barriers to using FES**

<b>Code</b>	<b>Responses</b>	<b>Group responding P/HCP/R</b>
<b>Layout</b>	i) Clearer instructions to go to the appropriate sections ii) Instructions before each section should be bolder and in larger print iii) The option ‘neither’ should be changed to ‘undecided’	i) 2 P* <sup>1</sup> and 2 HCP* <sup>2</sup> ii) 2P iii) 2P
<b>Training of members of staff</b>	i) “Members of staff were adequately trained to using FES” to be changed to “Members of staff were adequately trained in the use of FES” ii) “A lack of training in dealing with patients’ expectations...” to be changed to “A lack of training addressing patients expectations”	i) 2P ii) 2P and 2 HCP
<b>Research</b>	i) “Limited research showing the benefits of FES is a barrier to its application” - <i>deleted</i>	i) 2P/2 HCP
<b>Uncertainty about the benefit of FES</b>	i) “Some patients with SCI think the uncertainty about whether FES will work for them, make it not worth trying” - <i>deleted</i>	ii) 2 HCP/2R* <sup>3</sup>

\*1= Participant with SCI Group \*2 = Health Care Professional Group \*3=Researcher Group



## Figures



**Figure 1: Questionnaire development process**