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A feasibility study to investigate the clinical application of functional electrical stimulation (FES), for dropped foot, during the sub-acute phase of stroke – A randomised controlled trial

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ABSTRACT

Purpose: Functional Electrical Stimulation (FES), for dropped foot, has been shown to have positive benefits in chronic stroke. It has been suggested similar benefits may be seen earlier after stroke. The aim of this feasibility study was to evaluate the trial methodology of undertaking a randomised controlled trial (RCT) of FES in sub-acute stroke.

Method: This was a randomised feasibility study with non-blinded outcomes at six and twelve weeks. Sixteen sub-acute stroke in-patients with dropped foot were randomised into two groups (Control n=7; Intervention n=9). Both groups received routine gait re-education and an orthotic device, the control group used an ankle foot orthosis and the intervention group used FES. Outcome measures included gait velocity and cadence, Functional Ambulation Classification, Visual Analogue Scale of perception of walking and the Stroke Impact Scale.

Results: Eligibility criteria developed for inclusion of participants in the trial were appropriate. Set-up of FES during sub-acute stroke was feasible but more challenging than with chronic patients. Outcome measures were suitable and have informed the choice of measures for future work.

Conclusions: It is feasible to undertake a trial evaluating FES during the sub-acute phase of recovery after stroke. A larger randomised controlled trial is required.

INTRODUCTION

The annual global incidence of first ever stroke is estimated at 16 million [Strong, Mathers and Bonita, 2007]. Dropped foot, defined as the inability to elicit dorsiflexion during the swing phase of gait, occurs in about a fifth of the population with hemispheric stroke [Verdie et al, 2004; Laufer, Hausdorff and Ring, 2009 ;NICE, 2009].

One modality available for the management of dropped foot after stroke is functional electrical stimulation (FES). FES produces contractions in muscles paralysed due to central nervous system lesions by means of electrical stimulation to the peripheral nerve. This stimulation produces a functional movement for example activating dorsiflexors during the swing phase of walking [Kottink et al, 2007].

Evidence has emerged in recent years about the efficacy of FES in chronic stroke patients (>6 months post stroke) [Taylor et al, 1999a; Taylor et al, 1999b; Burridge, 2001; Penta et al, 2001; Kottink et al, 2004; Robbins, Houghton, Woodbury and Brown, 2006 ; Laufer, Hausdorff and Ring, 2009; NICE, 2009; Roche, Laighin and Coote, 2009; States, Salem, Pappas, 2009]. This evidence base has reported the positive benefits of FES including; reduction in energy expenditure, increased gait velocity, decreased falls and improved quality of life.

A number of authors [Granat et al, 1996; Robbins, Houghton, Woodbury and Brown, 2006; Roche, Laighin and Coote, 2009] have hypothesised that the benefits of FES, demonstrated in chronic stroke populations, may be replicated in the early phase of recovery after stroke. Granat et al, 1996, proposed that the application of FES in the

more acute setting may prevent abnormal gait problems becoming established in the longer term. Other potential benefits of applying FES early after stroke may include an ability to walk earlier, increased functional independence, earlier discharge home and improved motor recovery which may reduce the requirement for long-term use of FES or any orthotic device . (Taylor et al, 1999a; Yan, Hui-Chan and Li, 2005).

Possible secondary benefits may include an increase in confidence, general fitness and quality of life (Taylor et al, 1999a). These benefits could reduce the economic burden of stroke. However, to date, there has been very limited research evaluating the impact of FES immediately after stroke. This lack of research may be linked to the complexity of applying FES during the early stages after stroke or the difficulty of assessing its impact beyond that of routine recovery [Wade, 2009]. At present; only two studies have investigated the application of FES in acute stroke populations (< 2 weeks post stroke) [Kottink et al, 2004; Yan, Hui-Chan and Li, 2005; NICE 2008; Dunning et al, 2009] with no studies exclusively investigating FES during the sub-acute phase of stroke (two weeks to six months post stroke) [Kottink et al, 2004].

Yan, Hui-Chan and Li, 2005, undertook a trial with 46 participants, on average 10 days after stroke. Measures included the composite spasticity scale, ankle dorsiflexion torque and the percentage of participants able to walk. The results indicated that motor and walking ability was improved in the FES group. However, there was wide variability of outcome measure scores, a small sample size, short duration and non-functional application of FES. Dunning et al in 2009 reported two case studies of stroke patients to whom a peroneal FES device was applied less than two weeks after stroke. In contrast to Yan et al, the FES was applied in a functional context, during walking. Immediate improvements in function (timed up and go) and

gait speed (5 metre walk test) were measured in both participants. Further research is required in this acute stage after stroke.

Only a small number of studies have investigated the use of FES in sub-acute stroke patients, however these have been in combination with patients in a chronic phase [Bogataj et al, 1995; Granat et al, 1996; Sheffler, Hennessey, Naples and Chae, 2007]. One study, [Sheffler, Hennessey, Naples and Chae, 2007] included a sub-acute case study, but limited information was reported other than that following a period of FES the participant could ambulate without an AFO and had no adverse side effects. With no sub-analysis undertaken in the other studies [Bogataj et al, 1995; Granat et al, 1996] it is not possible to assess the impact of FES during the sub-acute phase of stroke. Work is required to investigate FES in sub-acute stroke populations.

The Medical Research Council publication 'Developing and implementing complex interventions: new guidance' [MRC, 2008] highlights the importance of adequate development and piloting of interventions, including practical issues, prior to testing in larger trials. This phase 1 feasibility study aimed to test the trial methodology when investigating FES during the sub-acute phase of stroke in preparation for a larger RCT. The key aims of this study were:

- To define the eligibility criteria of patients recruited to inform future trials.
- To identify any issues around the application of FES during the sub-acute in-patient phase of stroke.
- To collect outcome measures to inform future primary and secondary outcomes.

METHODS

Design

This was a randomised feasibility study with non-blinded outcomes.

Participants and recruitment

Ethical approval was sought and granted from the Lothian Research Ethics Committee. Patients admitted to the stroke rehabilitation unit at Astley Ainslie Hospital, Edinburgh and who fulfilled the inclusion and exclusion criteria, were approached and invited to participate by the clinical physiotherapist (JS). If patients wished to participate their written informed consent was sought prior to commencement of the study.

Eligibility criteria were developed by the research team (JS; LS) and were based on the literature and clinical experience in application of FES on a chronic stroke population. Criteria for inclusion in the study were (i) primary diagnosis of stroke; (ii) within four months of stroke; (iii) single dropped foot on side of hemiplegia; (iv) good skin condition; (v) no gross oedema of the lower limb; (vi) able to follow simple instructions; (vii) commenced assisted walking (able to walk a minimum of five metres' with moderate help of two or walking independently); (viii) able to give informed consent; (ix) medically stable. Exclusion criteria were: (i) single dropped foot due to lower motor neuron lesion; (ii) high tone in the calf and unable to achieve neutral passive dorsiflexion; (iii) pacemaker; (iv) uncontrolled epilepsy; (v) pregnancy; (vi) metal plate in lower limb.

Randomisation

Patients were allocated into either a control or intervention group using a computer generated simple randomisation list, no stratification was used. The computer generated randomisation list was created by a statistician, placed in consecutive numbered sealed opaque envelopes and held by the research physiotherapist (LS). Consecutively recruited patients were randomised according to the equivalent envelope.

Intervention

Control Group

The control group received routine gait re-education as part of physiotherapy (5 days per week for approximately 20 minutes). This included; balance re-education, facilitation of lower limb control, strengthening exercises and the provision of walking aids as required. An off the shelf ankle foot orthosis (AFO) was provided to correct the dropped foot during routine gait re-education. When participants were able to mobilise in physiotherapy with supervision; but no physical contact, safely and consistently, the AFO was provided to the patient to allow ongoing gait practice with the nursing staff in the ward environment. Patients who were independently mobile used an AFO to facilitate their gait as required throughout the day.

Intervention Group

The intervention group received the same routine gait re-education as the control group (5 days per week for approximately 20 minutes). FES was applied as an orthotic device for the correction of dropped foot during routine gait re-education. The FES device applied was the single channel Odstock Drop Foot Stimulator (ODFS) (Odstock Medical Limited, Salisbury, UK; NDI Medical, Cleveland, USA). The ODFS is a common peroneal nerve stimulator. Stimulation was provided via skin

surface electrodes and triggered by a pressure sensitive foot-switch worn inside the shoe and attached to the ODFS box. Within the stimulator box are specific parameters that are adjusted, by a trained professional, to suit the individuals gait pattern such as current amplitude, ramps and length of stimulation. In this study FES application was carried out by the study physiotherapist (JS), trained in the application of the ODFS. The stimulator was used during gait practice in physiotherapy. When the patient achieved the ability to walk with supervision, but no physical contact, safely and consistently in physiotherapy FES was provided to the patient to allow ongoing gait practice with the nursing staff in the ward environment. Patients who were independently mobile used FES to facilitate their gait as required throughout the day.

Outcome Measures

Outcome measures were collected within three specified components of the World Health Organisation International classification of Functioning, Disability and Health being Impairment, Activity and Participation. Outcome measures included a battery of standardised, published, validated measures to encompass the areas of interest including; a timed 10 metre walk test, which tested gait velocity and cadence [Mudge and Stott, 2007]; Functional Ambulatory Classification (FAC) on a scale of one to six measuring mobility independence [Holden et al, 1984; Holden, Gill and Magliozzi, 1986]; Stroke Impact Scale (SIS) measuring participation [Duncan et al, 1999] and a Visual Analogue Scale (VAS) measuring patients' perception of change in walking.

Gait velocity and cadence were measured using a timed 10 metre walk with a stopwatch to time and the number of steps counted over the same distance. Patients

walked at a self-selected pace using walking aids as required but with no physical assistance. It has previously been demonstrated that these measures are valid and reliable for use within stroke populations [Mudge and Stott, 2007]. The FAC classifies the level of ambulation into six categories. Scores of one to three indicate the need for physical assistance during ambulation, a score of four requires supervision only during walking, while a score of five or six represents two different levels of independent walking [Holden, Gill and Magliozzi, 1986]. Inter-rater reliability for the FAC has been established [Holden et al, 1984] although other aspects of validity and reliability have not been reported. The SIS is a stroke specific outcome measure developed to capture different dimensions of health-related quality of life in individual domains. These domains include strength, memory, emotions, communication, activities, mobility, hand function and participation. A composite recovery score is also calculated. Reliability, validity and sensitivity to change has been established and changes of approximately 10 to 15 points are deemed clinically meaningful. [Duncan et al, 1999]. The VAS of their perception of change in walking was an unvalidated VAS five point scale encompassing much worse, slightly worse, no change, slightly better and much better. The validity and reliability of VAS in stroke populations is poor and their use questionable [Price, Curless and Rodgers, 1999], however the VAS was included in this study as a gross indicator of the patient's perception of walking.

All outcome measures with the exception of the VAS were collected at baseline prior to randomisation. The full battery of outcomes were assessed at six and twelve weeks post randomisation. All data collection was undertaken by the study physiotherapist and was non-blinded (JS).

Statistical Analysis

Descriptive statistics were used to summarise baseline data. Median and inter-quartile ranges are reported as testing revealed non-normal distribution for the majority of the data. To test for statistical differences between the groups a Mann-Whitney U test was used. An intention to treat analysis was undertaken.

RESULTS

Potential participants were recruited between August 2006 & April 2007 and February 2008 & August 2008. Recruitment was suspended between May 2007 and January 2008 due to unforeseen staff absence and the commencement of an additional rehabilitation trial within the unit that led to potential participants being recruited into this other trial. There were 159 stroke patients admitted to the rehabilitation unit and screened for inclusion during the 16 months of active recruitment. In total 16 participants who met the eligibility criteria were approached for inclusion and all consented to participate in this feasibility study. This equated to an overall recruitment rate of 10% (16/159) with 100% (16/16) of all those approached consenting to be included in the study. Seven participants were randomised to the control group and nine to the intervention group. There were two deaths prior to data collection at 12 weeks, one from each group. Figure 1 provides a consort diagram.

INSERT FIGURE 1 ABOUT HERE

Table 1 summarises the participant characteristics at the time of entry into the study. The two study groups were similar in age, gender, side of hemiparesis and stroke

classification although the time since stroke was greater in the control group. This feasibility study had three key aims and the results will address each of these aims in turn.

INSERT TABLE 1 ABOUT HERE

Eligibility criteria

Of the 159 total admissions 143 were ineligible based on the developed criteria. A large proportion of those ineligible did not present with a dropped foot (n=85). Other reasons for ineligibility included a short length of stay (n=9); no assisted walking (n=9); inability to follow simple instructions (n=13); over 4 months since stroke (n=3); high tone (n=1); recruited to another trial (n=4); fragile skin (n=2) and missing data (n=17). Of those participants randomised to the intervention group the application of FES was unsuccessful for one participant only. This failure was as a result of significant tone in the calf, measuring a score of three on the modified Ashworth scale [Bohannon and Smith, 1987] measured in supine with the leg extended.

Factors that had affected on-going compliance with the application of FES, during this sub-acute phase, included: mood, confidence and the ability to engage with technology. Of interest, one participant in the study who met the inclusion/exclusion criteria and was allocated to the control group failed to achieve independent walking and was subsequently wheelchair bound.

Logistics around the application of FES

In this study FES was set-up by the clinical physiotherapist (JS) who had training and extensive experience of FES set-up in a chronic stroke population. In contrast to application of FES during the chronic phase it was found that during this sub-acute phase the set-up required regular adjustment and modification to accommodate for the fluctuating physical status. No adverse events occurred.

To facilitate and ensure compliance with FES outwith physiotherapy in the intervention group it was found that ongoing education for both ward-based staff and carers was necessary. Education required included set-up of the device; electrode and skin care; device maintenance and simple problem solving strategies in the event of stimulation failure.

Outcome Measures

The results of outcomes measured are reported in tables two and three. No statistically significant differences were found between groups for any of the outcome measures at six and 12 weeks. The rate of follow-up at each time-point was: 94% at six weeks (15/16) and 88% at 12 weeks (14/16). However, completion rates of individual outcome measures at the different time-points varied from 19% to 100%. The CONSORT diagram (figure 1) provides a summary of the numbers completing each outcome measure at each time-point. Reasons for non-completion of outcome measures included being unable to walk, poor comprehension, refusal to complete, fatigue and a lack of time to complete the full battery of outcome measures.

INSERT TABLES 2 AND 3 ABOUT HERE

Some participants failed to complete the full battery of outcomes. Only two outcome measures had the potential to be completed at all time-points (FAC and SIS) as the physical outcomes (gait velocity, gait cadence) could only be measured when participants were able to walk independently. The FAC achieved the highest completion levels (88%-100%) across the time-points. In contrast, the SIS achieved much lower completion rates due to issues such as poor comprehension of the participant, refusal to fill it in due to the nature of the questions and time restraints on the data collection by the researcher due to the length of the outcome measure.

Intention to treat analysis was carried out as not all participants in the intervention group were using FES at the time of outcome measurement. Of the nine participants in the intervention group, at six weeks, seven were using FES. By 12 weeks only three participants were still using FES to assist with walking. At six weeks, for one participant set-up of FES had been unsuccessful due to high tone and one participant no longer required the device as they had regained adequate active dorsiflexion. By 12 weeks one further participant no longer required the device due to recovery of active movement, one participant had died and two participants had stopped use due to low mood and confidence in their overall ability.

DISCUSSION

Overall, this study explored the feasibility of applying and evaluating FES during the sub-acute phase of stroke. The study has provided clarification about eligibility criteria and practical issues associated with the clinical application of FES during this

sub-acute phase of recovery after stroke. Furthermore, it has informed the choice of primary and secondary outcome measures for future studies.

Trial Design

This study recruited from a stroke rehabilitation unit with an overall average time to trial after stroke of 59 days. Targeting recruitment in the rehabilitation hospital only may have missed participants discharged directly home from the acute setting. In addition it was noted that the age of the population recruited into the study was considerably lower than the average age of the 143 participants screened for inclusion. In the control group one participant who met the inclusion criteria of assisted walking failed to walk independently. Future studies should consider recruiting from both acute stroke and rehabilitation units, ensure that older stroke populations are included and stratify at baseline by physical ability and age.

Eligibility Criteria

In this study recruitment rates of 10% of the whole stroke population passing through the stroke rehabilitation unit were achieved. It was identified that some patients excluded from this study could have been recruited if the eligibility criterion had been broadened. For example, if those patients with a short hospital length of stay had been provided with an out-patient follow-up service they could have used FES after discharge. A number of patients were unable to follow simple instructions, this could be addressed with the provision of additional support. For one participant the application of FES was unsuccessful due to high tone and it is proposed that in future high tone is defined as three or more on the modified Ashworth scale. Factors identified that affected on-going compliance with FES included mood, confidence and

the ability to engage with technology. Future studies should consider screening for these issues to assess their impact on the use of FES. Roche, Laighin and Coote, 2009 highlighted the need for further evidence to inform the selection of candidates for FES at this stage of recovery and this study contributes further knowledge which could be explored in more depth in larger studies.

Application of FES

In this study differences in set-up of FES between the chronic and sub-acute stroke populations were found by the clinical physiotherapist. During the chronic phase of physical recovery after stroke a plateau is often reached [Jorgensen, Nakayama, Raaschov, and Olsen, 1995] resulting in a relatively unchanging clinical presentation of impairments. In contrast, during the earlier phases after stroke, when a physical plateau has not been reached, change to impairments such as muscle tone is ongoing. As a result the application of FES during the sub-acute phase after stroke requires additional monitoring and frequent alterations to the set-up. In a multi-centre trial this could be difficult if clinical staff are inexperienced in the application of FES.

During this study FES was used in a functional manner, during walking, both within physiotherapy and the ward environment. This is in line with recommendations [Kottink et al, 2007; Robbins, Houghton, Woodbury and Brown, 2006] that patients should ambulate while using FES to increase the effectiveness of the intervention on gait. This study has demonstrated it is feasible to use FES in the sub-acute phase and it appeared to be safe with no critical incidents such as inappropriate use or falls occurring.

In the intervention group it was found that some participants no longer required FES. Some authors have highlighted the potential of FES to influence neuroplasticity [Burridge and Ladoucer, 2001; Roche, Lighin and Coote, 2009] during the early phase of recovery after stroke and these findings warrant the further investigation of the therapeutic effect of FES in the sub-acute phase of recovery.

Outcome Measures

A battery of outcome measures was collected and the study provided valuable information for future trial design. The completion rate between outcome measures varied. The FAC provided the most complete data-sets while the physical tests of gait speed and cadence highlighted some interesting results, particularly with regard to the orthotic versus therapeutic effect of FES. In some patients receiving FES there appeared to be a carry-over effect on their motor control when FES was removed. The use of VAS scores, while achieving reasonable completion in this study, have been questioned in stroke research due to issues of validity [Price, Curless and Rodgers, 1999].

The high completion rates of the FAC indicate it should be considered as a possible primary outcome in future trials. However, it is a relatively crude outcome measure. A power calculation (85% power with a 0.05 significance level) undertaken using FAC data from this study indicated that 200 participants would be required for each group to detect a difference. Applying a more sensitive physical measure may reduce the number of participants required. The Rivermead Mobility Index [Collen, Wade, Robb and Bradshaw, 1991] was identified as an alternative primary outcome measure for consideration in future studies. This measure is more sensitive than the FAC but

could still be administered easily in a large trial including by post or over the phone, hence increasing follow-up rates. In addition it is valid in both ambulant and non-ambulant populations. This is in contrast to physical measures which would require both the patient to be ambulant and a face to face visit. These physical measures should be considered as secondary outcomes. [Forlander and Bohannon, 1999]

Inclusion of measures of quality of life in studies evaluating FES have been recommended [Roche, Laighin and Coote, 2009] and the SIS was collected in this study. The SIS can provide detailed information about the impact of the intervention on health related quality of life. Although completion of this measure was affected by comprehension and the length of time required to complete all sections it would still be considered an important secondary measure in future studies. Consideration could be given to undertaking a qualitative study in a small sub-group to explore in detail participants perceptions of the impact of FES at this early stage.

In this study neither the intervention nor collection of outcome measures was blinded. Blinding of the intervention in rehabilitation trials is difficult to achieve [Wade, 2009] although in future studies an attempt to blind the collection of outcome measures should be made. In addition longer term outcomes should be collected to assess the long-term impact of FES for example six and twelve months after randomisation

An interesting finding was the shorter length of stay in the intervention group between randomisation and discharge home. In the control group (n=6) the average length of stay (median (IQR)) was 121.5 (49-176.5) days compared to 80 (52-115) days in the intervention group (n=8). Statistical analysis revealed no statistically significance

difference between the groups. This trend should be explored further in future studies and combined with an economic analysis.

This study has shown it is feasible to use FES in the sub-acute phase of recovery after stroke. Recommendations have been made to the eligibility criteria for patients in this phase after stroke. The study has identified and suggested strategies to address issues around the application of FES early after stroke. These suggestions could be implemented both in future research and clinical practice. The choice of primary measure in future studies would be limited by the population under investigation. The measure selected would need to reflect this and a simple questionnaire related to participants' level of independent walking may be more appropriate. However the importance of secondary measures to evaluate the therapeutic and orthotic effect of FES should not be negated. It is recognised that the small sample size of this study limits any inferences that can be made about the clinical efficacy of FES early after stroke. Further large scale studies are required.

CONCLUSIONS

This study has demonstrated the feasibility of applying FES for dropped foot during the sub-acute phase of recovery after stroke. No statistically significant differences were identified between groups for any outcome measures. However this study only had a small sample size. Despite this the experience gained and data collected has informed future trial design. A larger randomised controlled trial is required to explore the clinical effect of FES, both therapeutic and orthotic, during this sub-acute phase of stroke recovery.

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DECLARATION OF INTEREST

Authors report no declaration of interest.

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