



The Effectiveness of Peroneal Nerve Functional Electrical STimulation (FES) for the Reduction of Bradykinesia in Parkinson's: A Pragmatic Feasibility STudy for a Single Blinded Randomised Control Trial (STEPS)

Paul Taylor^{1,4}, Trish Sampson¹, Ben Beare² and Maggie Donovan-Hall³, Peter Thomas⁴, Val Stevenson², Coralie Seary², Elsa Marques⁵, Paul Strike¹, Sheila Nell⁶, James Lee¹, Diran Padiachy¹

¹Salisbury District Hospital, ²National Hospital for Neurology and Neurosurgery, ³Southampton University, ⁴Bournemouth University, ⁵University of Bristol, ⁶Parkinson's UK.

Objectives

STEPS aimed to gather information to help design of a multi-centre trial to demonstrate the clinical effectiveness of a treatment intervention called Functional Electrical Stimulation (FES). The treatment is intended to improve the walking of people who have Parkinson's. As STEPS was a relatively small study, it was not the intention that definitive results would be produced. Instead we aimed to test the feasibility of the study design, the acceptability of FES, determine recruitment and retention rates and calculate how many participants a future study would need to produce meaningful results. We also wanted to find out which of the aspects of walking that were changed by FES, were most important to the participants.

Background

FES is a means of producing movement in paralysed muscles and is commonly used to correct dropped foot for people with MS or Stroke. Dropped foot is the inability to lift the foot properly as it is swung forward while walking. Sticky pads called electrodes are placed on the side of the leg over the nerve that goes to the muscles that lift the foot. Stimulation is turned on and off at the right time using a pressure switch placed under the heel. Two small studies have indicated that FES may help to increase the speed of walking, increase step length and reduce freezing when used by people who have Parkinson's.

Methods

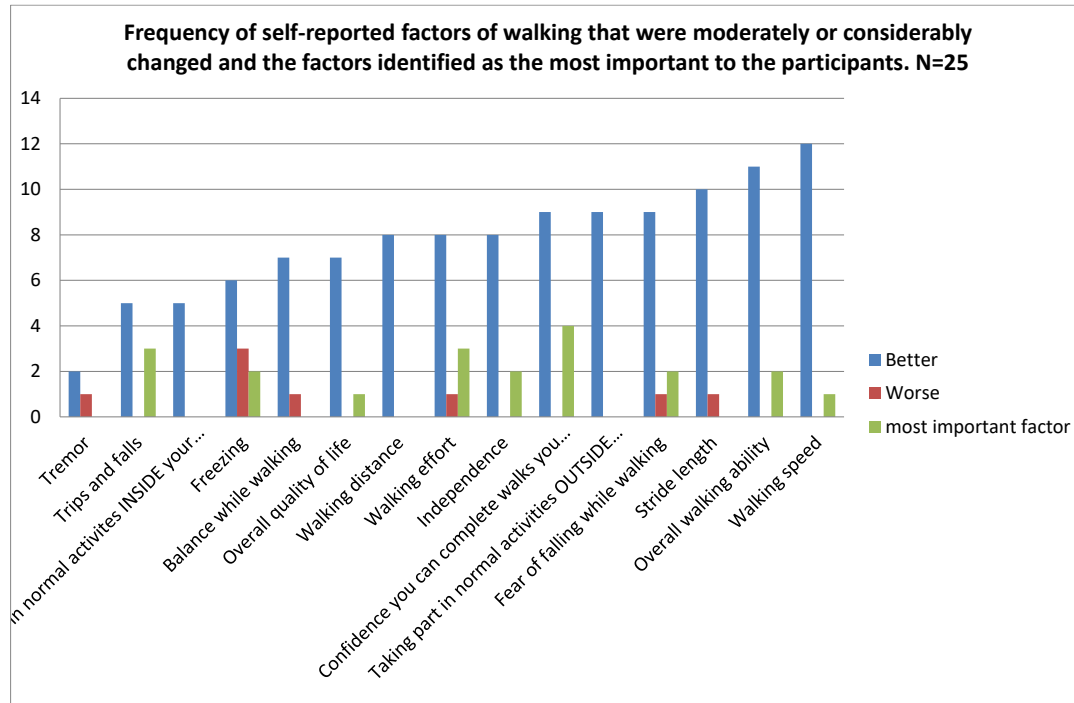
64 people with Parkinson's were recruited over 18 months to 2 centres, one in Salisbury and one in London. The participants were randomly allocated to either a control group who received normal care or a treatment group who received FES in addition to normal care. FES was used for 18 weeks followed by a reassessment 4 weeks after FES was stopped. We used a wide range of assessments to test the effect of FES in multiple aspects of Parkinson's. Assessments were done by an assessor who was blinded to the group allocation (Trish in Salisbury, Ben in London) to minimise the risk of bias. Participants who used FES were asked to say which aspects of their walking or Parkinson's symptoms were most changed after using FES.

Results

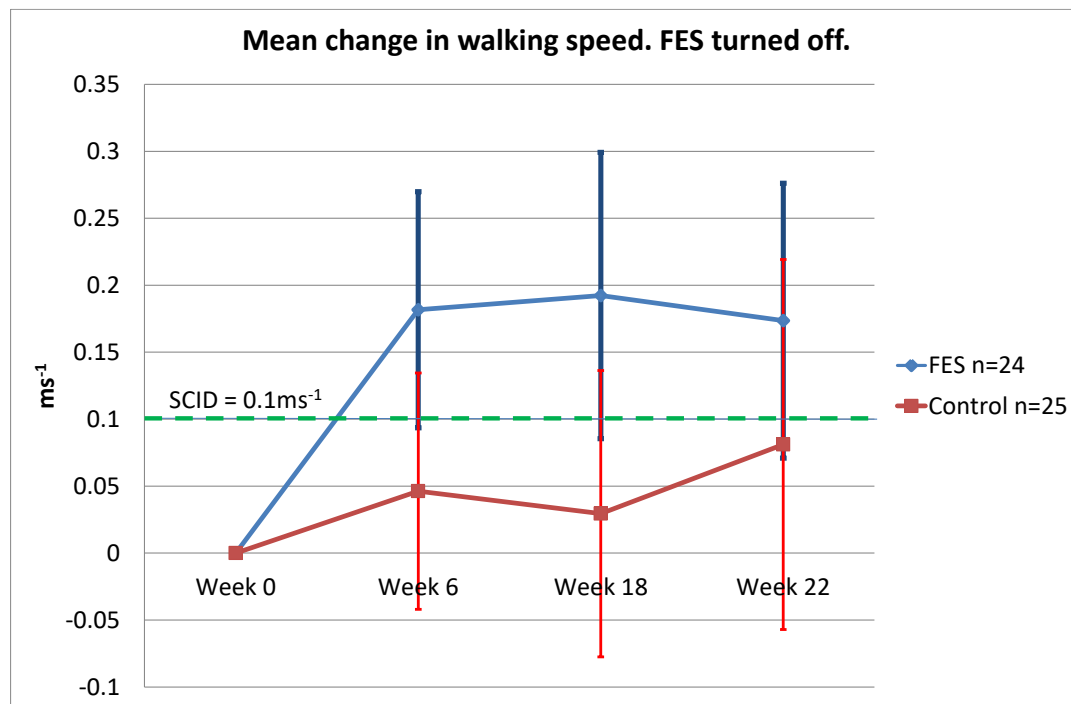
The recruitment rate was 1.8 participants per month per centre. 51 participants completed the study, a retention rate of 80%. The protocol was acceptable to most participants. The most



frequently reported effect of FES was on walking speed, followed by overall walking quality, increased stride length and reduced fear of falling (see graph 1). 21 of 32 participants who used FES achieved a “substantially clinically important difference” (SCID) in walking speed of at least 0.1ms^{-1} , indicating the improvement would have an effect on walking in daily life (graph 2).



Graph 1. The number of participants reporting moderate or considerable improvements.



Graph 2. Change in walking speed from the start. The vertical bars represent the “confidence interval”, which is a measure of the precision of the result. A larger study would increase the precision (smaller bars). Measurements at week 22 were 4 weeks after FES use stopped.



Participant Feedback

Participants were asked about their experiences of taking part in the study. Positive comments included the following: “All about confidence in walking. Leads to independence”; “FES has helped with my confidence, which makes a big difference and is a good thing.”; “I was dancing with everyone at a wedding on Saturday. Before FES I would be sat down watching.”; “Reduced fear of doing stuff. Overcomes the embarrassment of looking like you're drunk (walking).”

However there were some negative comments as well: “Too itchy to wear”; “I am very self-conscious of the visibility of the device and wires particularly when I am travelling on the tube.”; “You have to be very dedicated to fix up each morning. Method of wearing needs to be improved.”; “Screen difficult to read. Need to be dexterous to use.”

It was reported by some that the effect of the FES was long lasting “Not used a lot. It’s like re-calibrating. Once a week is enough. An amazing difference. Can’t praise it enough.”

Conclusions

The STEPS study demonstrated that FES can be used with people who have Parkinson’s and that the research protocol was feasible to achieve. The results indicate that walking speed should be the main outcome measure for a future study but it is also important to record other factors, because people responded to FES in multiple ways. From the results we can calculate that the next study should have 470 participants, 235 in each group. We will need to have 9 centres recruiting for 30 months to achieve this.

Acknowledgments

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Funder’s Statement

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