Journal of Physiotherapy xxx (2016) xxx–xxx

Journal of PHYSIOTHERAPY
journal homepage: www.elsevier.com/locate/jphys

Research

Functional electrical stimulation cycling does not improve mobility in people with acquired brain injury and its effects on strength are unclear: a randomised controlled trial

Davide G de Sousa [a,b,c], Lisa A Harvey [b,c], Simone Dorsch [d], Joan Leung [e], Whitney Harris [f]

[a] Graythwaite Rehabilitation Centre, Ryde Hospital; [b] John Walsh Centre for Rehabilitation Research, Kolling Institute, Northern Sydney Local Health District; [c] Sydney Medical School Northern, University of Sydney; [d] School of Physiotherapy, Australian Catholic University; [e] Royal Rehab, Ryde; [f] Prince of Wales Hospital, South Eastern Sydney Local Health District, Sydney, Australia

KEY WORDS

Functional electrical stimulation
Stroke
Acquired brain injury
Physical therapy
FES cycling

ABSTRACT

Question: Does 4 weeks of active functional electrical stimulation (FES) cycling in addition to usual care improve mobility and strength more than usual care alone in people with a sub-acute acquired brain injury caused by stroke or trauma? **Design:** Multi centre, randomised, controlled trial. **Participants:** Forty patients from three Sydney hospitals with recently acquired brain injury and a mean composite strength score in the affected lower limb of 7 (SD 5) out of 20 points. **Intervention:** Participants in the experimental group received an incremental, progressive, FES cycling program five times a week over a 4-week period. All participants received usual care. **Outcome measures:** Outcome measures were taken at baseline and at 4 weeks. Primary outcomes were mobility and strength of the knee extensors of the affected lower limb. Mobility was measured with three mobility items of the Functional Independence Measure and strength was measured with a hand-held dynamometer. Secondary outcomes were strength of the knee extensors of the unaffected lower limb, strength of key muscles of the affected lower limb and spasticity of the affected plantar flexors. **Results:** All but one participant completed the study. The mean between-group differences for mobility and strength of the knee extensors of the affected lower limb were −0.3/21 points (95% CI −3.2 to 2.7) and 7.5 Nm (95% CI −5.1 to 20.2), where positive values favoured the experimental group. The only secondary outcome that suggested a possible treatment effect was strength of key muscles of the affected lower limb with a mean between-group difference of 3.0/20 points (95% CI 1.3 to 4.8). **Conclusion:** Functional electrical stimulation cycling does not improve mobility in people with acquired brain injury and its effects on strength are unclear. **Trial registration:** ACTRN12612001163897. **[de Sousa DG, Harvey LA, Dorsch S, Leung J, Harris W (2016) Functional electrical stimulation cycling does not improve mobility in people with acquired brain injury and its effects on strength are unclear: a randomised controlled trial. *Journal of Physiotherapy* XX: XX-XX]**

Introduction

Walking and moving around are some of the most important goals for people with acquired brain injury caused by stroke or trauma. Often, however, these goals are not achieved. For example, one estimate indicates that 40% of stroke survivors who are unable to walk on admission to rehabilitation are still unable to walk at 3 months.[1] To improve the ability to walk and move around, people with acquired brain injury require intensive repetitive practice[2,3] in combination with interventions that address impairments such as weakness.[4,5] However, many patients in rehabilitation spend only 1 hour per day with a physiotherapist and are inactive for as much as 70% of the day.[6–8] One reason for this inactivity following acquired brain injury is that those who are very immobile and weak have few options for exercising independently; they often require assistance from two or more physiotherapists, which is costly and time consuming.

Functional electrical stimulation (FES) cycling may help overcome this problem because patients can cycle without physical assistance from physiotherapists. Functional electrical stimulation cycling involves the application of a small electrical current through the skin to stimulate muscle contractions in synchrony with the pedalling motion of a lower limb ergometer. If used in addition to routine face-to-face physiotherapy, FES cycling may increase strength in the lower limbs, which may have carryover effects on the patient's ability to walk and move around.

There are two recent systematic reviews of electrical stimulation (ES) and FES on the upper and lower limbs in people with stroke.[9,10] Both indicated improvements in function, including mobility, and one also showed increases in strength. However, neither of these two reviews looked at the effect of FES cycling. There are four studies that have specifically looked at FES cycling in sub-acute hemi-paretic patients.[11–14] Two of these studies did not measure strength[13,14] or mobility,[13] and had small sample sizes ($n \leq 20$). The

http://dx.doi.org/10.1016/j.jphys.2016.08.004

other two studies are relevant to the question of whether FES cycling has therapeutic effects. The first study suggested increases in lower limb strength but not walking,[11] and the second suggested the opposite, namely: improvements in walking but not lower limb strength.[12] It is therefore unclear whether FES cycling is therapeutic. Interestingly, in the study that showed a treatment effect on strength, participants were instructed to remain passive and not actively contribute to the cycling.[11] Remaining passive while cycling is not in keeping with current research on neural plasticity, which suggests that purposeful active movement is essential.[15,16] It would seem more likely that FES cycling would need to be combined with maximal voluntary effort from patients to see carryover effects on mobility and strength. It is worth trying to better understand whether FES cycling is potentially therapeutic because it is a relatively inexpensive intervention that does not require direct assistance from a physiotherapist.

Therefore, the research question for this multi centre, randomised, controlled trial was:

Does 4 weeks of active FES cycling in addition to usual care improve mobility and strength more than usual care alone in people with a sub-acute acquired brain injury caused by stroke or trauma?

Method

Design

An assessor-blinded, randomised, controlled trial was undertaken (Figure 1). Using computer software,[a] a person not involved in the trial created a blocked random allocation schedule for 40 participants. The blocking ensured equal numbers of participants in the two groups. Participants' allocations were placed in opaque, sequentially numbered and sealed envelopes that were held off-site by a person not otherwise involved in the trial. Once a participant passed the screening process and completed the initial assessment, trial staff contacted the independent person, who opened the next envelope and revealed the group allocation. The participant was considered to have entered the trial at this point. The trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR: 12612001163897), however, one of the secondary outcomes was erroneously omitted from the trial registry, although it was included in the protocol and is reported here. The authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed.

Participants

All patients admitted to three sub-acute adult rehabilitation units between 11 February 2013 and 21 October 2015 were screened for inclusion. The inclusion criteria were: first time stroke or any other non-progressive acquired brain injury; hemiparesis with composite strength in the affected lower limb $< 19/20$ points; less than 6 months after acquired brain injury; ability to sit supported for 40 minutes; and sufficient communication skills to indicate yes/no verbally or via gestures. Patients were excluded for the following reasons: limited joint range of movement or a musculoskeletal condition preventing use of the lower limb cycle; cardiac pacemakers; inability to tolerate the ES; pregnancy; absence of notable contraction of lower limb muscles with ES; or unstable medical conditions.

Interventions

Participants allocated to the experimental group received an incremental progressive, individualised FES cycling program,

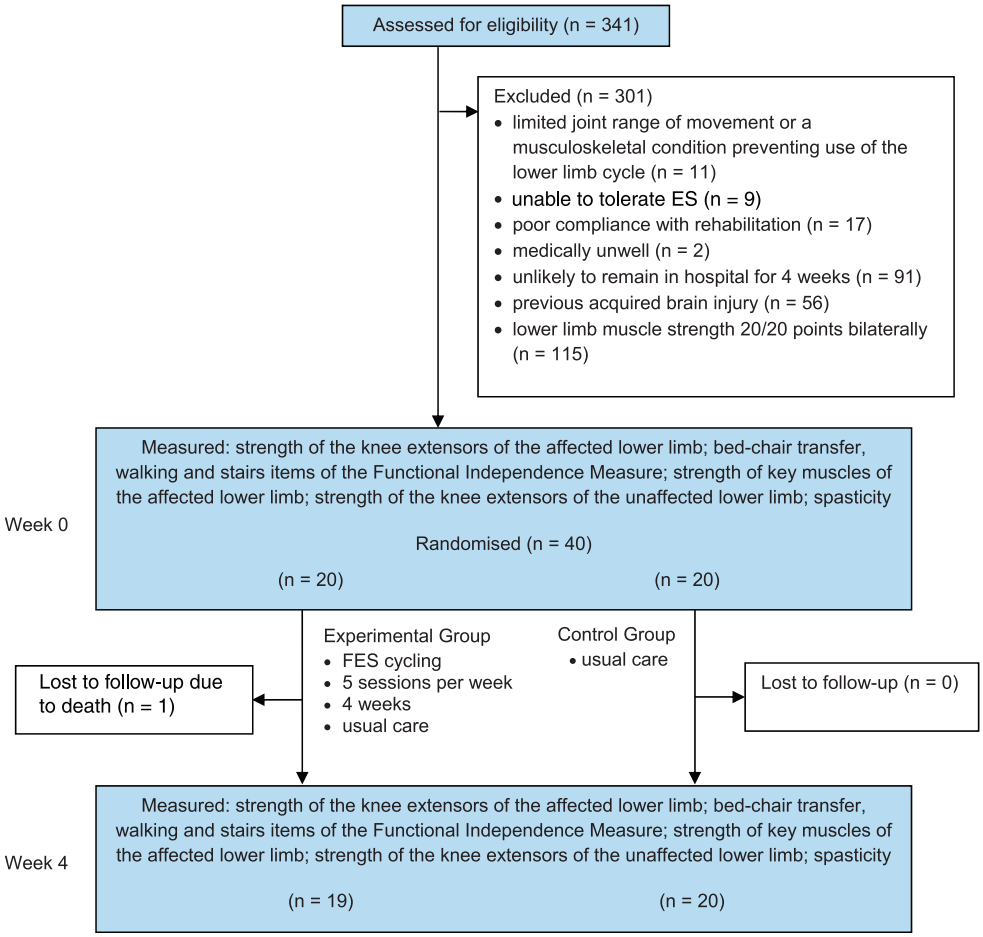

Figure 1. Flow diagram.

Please cite this article in press as: de Sousa DG, et al. Functional electrical stimulation cycling does not improve mobility in people with acquired brain injury and its effects on strength are unclear: a randomised controlled trial. *J Physiother.* (2016), http://dx.doi.org/10.1016/j.jphys.2016.08.004