

<b>Project Title:</b>	Neural and biomechanical correlates of response to the use of an ankle-foot cast provided to improve walking recovery early after stroke. A Phase II trial.
<b>Project Ref:</b>	08-43-25
<b>Cost:</b>	£926,697
<b>Lead Applicant &amp; Institution:</b>	Professor Valerie Pomeroy Health and Social Sciences Research Institute University of East Anglia
<b>Start Date:</b>	1 November 2009
<b>Plain English Summary:</b>	<p>Weakness of the leg and foot is common after stroke. This affects peoples' everyday lives. For example, being unable to cross the road in the time allowed at most Pelican crossings. Current therapies often have disappointing outcomes. Some treatments may be beneficial but this largely depends on patients' ability to participate actively in functional exercise. Patients with substantial weakness, however, those who most need therapy, may not be able to do this. A common problem limiting ability to practice walking is when the affected foot cannot be held in the correct position in relation to the lower leg. The present study will investigate whether a splint designed to maintain a correct position of the foot on the leg will enable people to participate in more walking re-training and thus have a better outcome after stroke.</p> <p>The proposed study will be a two-group clinical trial. All participants will receive standardised conventional physical therapy. Participants will be randomly allocated to receive either the splint (called a soft-scotch ankle-foot cast) or no extra intervention. The outcome measures that will be used to assess whether the splint is beneficial will be: walking speed and ability to walk independently. The measures will be made before treatment begins, after 6 weeks treatment and 6 months after stroke. The trial is designed to find whether the benefits of using the splint justify a subsequent larger trial.</p> <p>Embedded in the trial are some measures which aim to increase understanding of how the central nervous system (brain and spinal cord) recovers after damage caused by stroke. We know that central nervous system recovery occurs due to reorganisation of nerve networks in the brain and spinal cord. We do not know how we can use physical therapies to encourage beneficial reorganisation so that we can improve outcomes for stroke survivors. We also do not know which stroke survivors should receive which physical therapies.</p> <p>Neuroimaging of the brain has provided our current understanding but this cannot extend our general understanding into the specifics that we need to guide treatment decisions to improve ability to walk after stroke because of</p>

	<p>technological limitations. A way forward is provided by using biomechanics to investigate biological mechanisms of walking recovery after stroke (e.g. how movement at different joints is co-ordinated and how muscle activity moves body segments and maintains balance). Biomechanics involves measurement of movement and postural control during walking in free space without application of either radiation or magnetic fields. We will combine brain imaging to define the stroke damage with biomechanics to define the biological mechanisms of walking with clinical measures of ability to walk. We will therefore be able to find how the biological mechanisms of walking change over time in the two groups of participants and whether these changes are associated with improvements in ability to walk. Thus we will gain insight as to how different forms of physical therapy might be working in stroke survivors with different parts of their brain damaged by the stroke.</p> <p>The protocol for this clinical trial will be submitted for Ethical Approval before beginning to recruit participants. The trial will only begin when ethical approval has been granted. Every person recruited as a participant in this clinical trial will first be required to provide written informed consent. No routine treatment will be with-held from participants in this clinical trial whether people are allocated to the splint group or not.</p> <p>The trial team have considerable expertise in stroke rehabilitation research. the team is multidisciplinary with expertise including medicine, physiotherapy, neuroimaging, bioengineering, statistics and user involvement. In addition, key members of the team are senior researchers in the centres in which this clinical trial will be undertaken.</p>
<p><b>Abstract:</b></p>	<p><u>Design:</u> Randomised, controlled, observer-blind Phase II trial to determine efficacy of a SSAFC for enhancing walking recovery with embedded exploratory investigation of neuro-biomechanical prognostic indicators for and mechanisms of response to a individualised and rapidly produced ankle-foot cast (SSAFC) and protocol-driven conventional physical therapy (CPT).</p> <p><u>Setting:</u> Participants will be recruited from in-patient stroke services and will be followed up until 6 months after stroke.</p> <p><u>Target Population:</u> Adults aged 18+ years, 3-42 days after stroke, confirmed by routine clinical imaging; fit for rehabilitation; walking ability from FAC score 1 to FAC score 5 but with a) abnormal initial floor contact and/or b) impaired ability to take full body weight through the paretic lower limb in stance; no contractures at hip, knee, ankle or forefoot or loss of skin integrity over the paretic lower limb; and can follow a 1-stage command i.e. sufficient communication for this trial.</p> <p><u>Interventions:</u> Participants will receive conventional physical therapy (CPT) provided by the clinicians using our published standardised treatment schedule. Those allocated to the experimental group will also receive a soft-scotch ankle-foot cast (SSAFC). The intervention phase will last for six weeks.</p> <p><u>Outcomes And Duration Of Follow-Up:</u> The primary clinical measure will be walking ability measured by walking speed. Secondary clinical measures will be: the FAC, the Modified Rivermead Mobility Index and efficiency of gait (e.g. knee angular velocity, step time symmetry and step length symmetry).</p> <p><u>Sample size</u> 110 patients required.</p>

<b>ISRCTN: (if applicable)</b>	39201286
<b>Project Protocol:</b>	<a href="http://www.eme.ac.uk/projectfiles/084325protocol.pdf">www.eme.ac.uk/projectfiles/084325protocol.pdf</a>
<b>Project website: (if applicable)</b>	To follow
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