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What is This?
The effects of transcutaneous electrical nerve stimulation on strength, proprioception, balance and mobility in people with stroke: a randomized controlled cross-over trial

Sarah F Tyson¹, Ebrahim Sadeghi-Demneh²,³ and Christopher J Nester²

Abstract
Objective: To investigate the feasibility and potential efficacy of ‘activeTENS’ (that is transcutaneous electrical nerve stimulation (TENS) during everyday activities) by assessing the immediate effects on strength, proprioception, balance/falls risk and mobility after stroke.
Design: A paired-sample randomized cross-over trial.
Subjects: Twenty-nine mobile chronic stroke survivors with no pre-existing conditions limiting balance or mobility or contra-indications to TENS.
Setting: University clinical research facility.
Intervention: A single session of ‘activeTENS’ delivered via a ‘sock electrode’ (70–130 Hz, five second cycle) plus a session of control treatment (wearing the sock electrode with no stimulation), lasting approximately two hours in total.
Main Outcomes: Dorsiflexor and plantarflexor strength and proprioception using an isokinetic dyanometer, balance and falls risk (Standing Forward Reach Test) and gait speed (10-m walk test).
Results: All participants tolerated ‘active TENS’. Most parameters improved during stimulation with activeTENS; balance (p = 0.009), gait speed (p = 0.002), plantarflexor strength (p = 0.008) and proprioception of plantarflexion (p = 0.029), except dorsiflexor strength (p = 0.194) and dorsiflexion proprioception (p = 0.078).
Conclusions: The results provide initial evidence of the potential of ‘active TENS’ to benefit physical function after stroke which warrants further phase II trials to develop the intervention. Concerns that stimulation could have a detrimental impact on balance and increase risk of falls were not supported.

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Introduction
Transcutaneous electrical nerve stimulation (TENS) increases cortico-motor excitability of the areas for the body part(s) that have been stimulated and the excitability may outlast the period of stimulation.1–5 Hence it is postulated that supplementing sensory input using TENS may facilitate long-term neuroplastic changes and enhance motor recovery after stroke. TENS is readily available, inexpensive and relatively easy to apply so, if effective, would be relatively simple to use as part of a rehabilitation programme or in everyday life.

Several trials have suggested that TENS applied to the lower limb can have beneficial effects on spasticity, strength and mobility but, systematic reviews have concluded that further trials are needed to overcome methodological short-comings and develop the intervention more thoroughly.6,7 One potentially important aspect of that development is to consider how the TENS is delivered. Previous trials of TENS for people with stroke have delivered the TENS contemporaneously, but separately, to therapy or training sessions8–12 or with no other treatment.13,14 In providing the stimulation while inactive, these trials may have limited the effect as the cortical activation during treatment is related to the functional gain;15 indicting that it would be desirable to deliver TENS in ways that maximises excitation during treatment. Furthermore, it is important for functional recovery to practice in a relevant environment so that improvements carry over into everyday life.16 Thus, we hypothesise that TENS may enhance everyday activity if used during everyday activities, rather than while inactive.

Our aim is therefore, to investigate the feasibility and potential efficacy of TENS during everyday life (or ‘activeTENS’) on lower limb impairments (strength, proprioception) and activity limitations (balance and mobility). Although there is a good theoretical rationale and some evidence for this from a previous case report,17 there is an alternative argument that supplementary stimulation while active could be harmful as the additional attentional demand of perceiving the supplementary sensory stimulation could distract a stroke survivor’s capacity to balance or walk safely. Thus, in line with the MRC (Medical Research Council) Framework for the Development and Evaluation of Complex Interventions18 we undertook an exploratory trial of the effect of ‘activeTENS’ on falls risk to tell us whether we should precede to further trials and, if so, to obtain data to inform the choice of parameters and sample size calculations for future trials.

Method
A paired sample, randomized cross-over trial of the immediate effects of activeTENS was used in which the participants acted as their own control and the randomization came from the order in which the TENS or control was given (which provided blinded allocation of which treatment came first). Blinded group allocation was not an issue as all patients received both the control and stimulation condition. All participants completed both control and stimulation conditions and all testing procedures. To blind the participants as far as possible to the treatment received, they were told that they would receive two types of stimulation that they may, or may not, be able to feel, without specifying which we thought may be the more effective. Further details of the randomization process are found in the section on the testing protocol and outcome measures.

After ethical approval from the University’s Research Ethics Panel, we recruited a convenience sample of stroke survivors through local community stroke groups and/or the research group’s database.
of study volunteers. They were community-dwelling stroke survivors, who had completed their rehabilitation, had enduring balance and/or mobility limitations but were able to stand for at least 30 seconds without assistance (with walking aids if necessary), able to consent and travel to the University’s clinical research facility for testing and had no pre-existing conditions limiting balance or mobility or contradictions to TENS to the leg (cardiac pacemaker or skin lesions over the lower leg).

The TENS was delivered using a Biostim® M7 TENS unit (Biomedical Life Systems, Princeton, USA) with a conductive (ankle length) sock that stimulates the whole foot and ankle. Participants wore conductive socks on both feet but only the one on the affected foot was connected to the TENS machine (iSock, TensCare Ltd, Surrey, UK). The sock has the advantages that it is easier to put on than gel electrodes, does not produce the allergic reactions occasionally seen with gel electrodes and enables a larger area of stimulation, which is desirable.1–5,19,20 The sock’s manufacturer recommends that it should be dampened to maximise conductivity of the stimulation. However, pilot work showed that this was impossible to standardise and participants found it unacceptable to wear a damp sock inside their shoe, so the sock was used in a dry condition.

A biphasic symmetrical stimulus with phase duration of 50 µs and ranging frequency of 70–130 Hz over a five second cycle was used. This frequency modulation was to prevent habituation of receptors and cover the optimal frequency for all participants, which is specific to each individual but is around 100 Hz. Stimulation intensity was increased until each participant reported a comfortable tingling or buzzing feeling over their foot and/or ankle without muscle activation or radiation to proximal body segments. Participants were encouraged to increase the stimulation if they felt it was ‘wearing off’ during the session; however none felt the need to do so. As our goal was to develop the intervention during everyday activities we did not specify the duration of the stimulation, but encouraged participants to move around and use it until they felt comfortable and had ‘got used’ to the sensation then we tested them while stimulated. The stimulation was maintained during all of the familiarisation and testing procedures of the ‘stimulation’ phase.

When tested without the stimulation (the control condition) the participants indicated when they felt the stimulation had ‘worn off’ and were then tested. For the control treatment, the sock and TENS was applied in the same way and the machine was turned on but no stimulation was given. During this familiarisation period, most participants walked around the building or the movement laboratory and/or practiced balance tasks (such as shifting their weight from one foot to another). Some went to the toilet and others went to the café for a cup of tea. We did not formally record the activity or length of time taken, however the total intervention and testing time lasted approximately two hours.

All testing was completed in a single session. After informed consent was obtained, the TENS socks were put on, the TENS machine was attached to the sock on the weak side and the participant was randomized (by them selecting a concealed envelope from a bag) to receive either the stimulation or the control condition first.

Once the TENS had been set up, the participant was encouraged to move and walk around to familiarise themselves with the sock (± the stimulation). Once they felt comfortable and confident the following testing protocol was undertaken. The order of tests, performed with and without TENS stimulations, was block randomized to avoid any order effect. The testing using the Biodex Isokinetic Dyanometer (ankle proprioception and strength) was completed in one block and the balance and mobility tests in another. The participants were free to move around or rest at their convenience during and in-between the testing.

For all parameters, the test was explained and demonstrated to the participant who then practiced as often as they liked until they felt comfortable. The isokinetic dyanometer tests were repeated six times (three in each direction in random order) and mean values were calculated. The falls risk/balance and mobility tests were measured twice and mean values calculated after an initial ‘practice run’.21
Proprioception detection threshold

Proprioception detection threshold was assessed by evaluating joint position sense of the ankle in dorsiflexion and plantarflexion using a Biodex® Isokinetic Dynamometer. Participants sat in the Biodex® chair with their eyes closed to eliminate visual input. Their weak foot was placed on the footplate and their position was adjusted so that the knee was comfortable (~70 degrees flexion) and secured with a Velcro belt across the chest, pelvis and thigh. The participants’ ankle was passively moved from a neutral position into either dorsiflexion or plantarflexion at 0.25°/s to avoid stretch on peri-articular structures and reduce cues from the footplate following acceleration. They indicated when they detected movement at the ankle using a hand-held trigger that recorded the angle and verbally indicated the direction of movement.

Strength

Maximum isometric plantarflexor and dorsiflexor strength was assessed using standard operating procedures for the dynamometer with the ankle in a neutral position (90 degrees). For plantar flexion, participants pressed their foot downward as hard as possible against the footplate and then pulled it upward as strongly as possible (dorsiflexion).

Balance and falls risk

The Standing Forward Reach Test is a well-established measure of balance and a proxy measure of falls risk (in that the further the subject can reach, the lower their risk of falling, with a reach beyond 10 cm/4 in considered a critical value). The distance the participant can reach forward beyond arm’s length while standing with an outstretched arm at shoulder height was measured.

Mobility

The 10-m walk test evaluated mobility; participants walked this distance at their self-selected pace, which was recorded with a stopwatch and velocity (m/s) calculated.

Paired t-tests compared the outcome measures with and without TENS. To obtain an insight into the clinical significance of any changes, the mean difference between the control and intervention, and the percentage change (of the control value) for each parameter, were calculated.

Results

Twenty-nine stroke survivors were recruited, (15 women), mean age of 64.5 years (SD 12.6, range 28–82). Sixteen had a right-sided hemiplegia, 11 were left sided and two had a bilateral weakness (for whom stimulation was given to the weaker foot). Mean walking speed was 0.74 m/s (SD 0.31); eight (28%) were ‘physiological walkers’, five (17%) were ‘household’ walkers’, seven (24%) were ‘limited outdoor walkers’ and nine (31%) were ‘unlimited outdoor walkers’ according to the Walking Handicap Scale.

All participants tolerated the stimulation and found it acceptable. One could not feel any stimulation even at maximum intensity and with the TENS sock dampened, however she continued with the testing and reported a positive effect with stimulation (which was borne out by the objective measurements). One participant reported that his leg was painful after the treatment but this had resolved the next day, no other adverse events were reported. Participants performed significantly better in balance, mobility, plantarflexor strength and plantarflexor joint position sense (p = 0.009–0.029, Table 1), but there was no effect on dorsiflexion strength (p = 0.194) and joint position sense (p = 0.078).

Discussion

Our results show that it is feasible and acceptable to provide supplementary sensory stimulation using a TENS sock to stroke survivors while active, which warrants further investigation. One of our concerns in undertaking this trial was the possibility that supplementary stimulation while active
could be detrimental and increase falls risk, as it could increase the cognitive demands of perceiving and processing the additional afferent information, which could detract from the attention available for balance and mobility tasks, thereby increasing the potential for falls or could have interfered with the afferent signals from the joints so that movement was not perceptible. Our results do not support this hypothesis: performance on the Standing Forward Reach Test (a well-establish measure of balance and falls risk) during activeTENS improved suggesting, if anything, a reduction in falls risk. Improved awareness and activation of plantarflexion was also seen, which may reduce the tendency to trip or catch ones toes (a common cause of falls) if used for longer periods. Only one (minor) adverse event was reported. Thus, we plan to develop ‘activeTENS’ during everyday activities with further trials.

This was an exploratory trial of the immediate effects of ‘activeTENS’. It fulfilled its aims and showed that ‘active TENS’ could affect strength, proprioception, balance and mobility, which support further trials to develop the intervention, particularly to investigate the effects of longer-term use before progressing to a definitive trial. However, inference cannot be drawn about the effects (or effectiveness) of its use during rehabilitation, the acute stages of recovery, or of prolonged use. The data indicate a variable response to the intervention so, although we would recruit a pragmatic sample in the first instance, further work is needed to identify characteristics of stroke survivors who are likely to benefit from ‘activeTENS’ and to identify the most effective dose of stimulation in terms of the intensity, frequency and burst pattern of the electrical stimulation.

Previous studies have shown that a single 30 minute session of TENS can improve function immediately afterwards, but the current results are the first to assess the effects of TENS during stimulation and while mobile. They suggest that the effects of TENS are almost immediate. However the fact that we found a difference between stimulation and control conditions indicates that there is negligible carry-over effect once stimulation stopped and our evidence of effect is limited to the period of stimulation. The few previous trials of TENS to the lower limb, which have included a follow-up period, provide conflicting results. Sonde et al. and Yan and Hui-Chan found that the effect of TENS was lost at follow-up, but Shamay et al. reported sustained changes. These were stronger in the group who received task-related training plus TENS, rather than TENS alone, suggesting that TENS needs to be combined

| Table 1. The effects of TENS on mobility, balance, strength and proprioception in people with stroke. |
|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|
| Mean (SD) | Mean difference (P values (95% CI)) | |
| Forward reach (cm) | Control = 18.2 (6.86) | 4.16 (7.87) | 0.009 |
| | TENS = 19.88 (7.16) | 10.9% (17.7) | (–2.91, –0.45) |
| Velocity (m/s) | Control = 0.74 (0.31) | 0.03 (0.04) | 0.002 |
| | TENS = 0.77 (0.33) | 3.9% (6.5) | (–0.04, –0.01) |
| Plantarflexor strength (Newton/m) | Control = 25.93 (12.73) | 4.34 (7.95) | 0.008 |
| | TENS = 30.27 (15.73) | 18.5% (36.0) | (–7.42, –1.26) |
| Dorsiflexor strength (Newton/m) | Control = 9.45 (8.26) | 1.32 (5.14) | 0.194 |
| | TENS = 10.77 (7.68) | 91.5% (328.7) | (–3.35, 0.71) |
| JPS plantar flexion (degrees) | Control = 5.87 (5.66) | –1.80 (4.78) | 0.029 |
| | TENS = 4.17 (3.21) | –4.7% (68.1) | (0.19, 3.16) |
| JPS dorsiflexion (degrees) | Control = 5.65 (5.28) | 1.67 (3.43) | 0.078 |
| | TENS = 3.85 (3.18) | 9.5% (58.1) | (–0.22, 3.82) |

A negative value for joint position sense indicates an improvement (in that the movement was detected after less joint movement). CI, confidence interval; JPS, joint position sense; TENS, transcutaneous electrical nerve stimulation.
with activity to optimally sustain changes in performance. This supports the notion of using TENS during everyday activity. Dose–response studies are needed to establish the amount and duration of stimulation needed to produce sustained change. It is possible that TENS does not facilitate sustained changes in motor function, but could still be used in the long-term to provide an orthotic, rather than ‘curative’ effect.

Clinical messages

- ActiveTENS using a sock electrode is a feasible and acceptable way to provide supplementary sensory stimulation to chronic stroke survivors and shows promise as potential intervention to improve strength and joint position sense, balance and mobility. Further trials to develop the intervention are warranted.
- Initial concerns that ‘ActiveTENS’ could make balance worse and increase the risk of falls was not supported.

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References

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