CWY Hui-Chan 許陳雲影
SSM Ng 伍尚美
MKY Mak 麥潔儀

Effectiveness of a home-based rehabilitation programme on lower limb functions after stroke

Key Messages

1. Home-based rehabilitation programmes using a combination of transcutaneous electrical nerve stimulation (TENS) with task-related training (TRT) achieved superior results to the use of either of these interventions alone for improving motor functions in post-stroke patients whose strokes occurred 4.3 to 5.0 years previously.
2. The TENS is particularly useful as complementary therapy in a home-based TRT programme for patients with chronic stroke.

Introduction

Stroke is a major cause of disability and handicap in adults. With an increasing incidence of first-ever strokes and a decreasing mortality rate, more stroke survivors are returning home rather than entering formal inpatient rehabilitation programmes. The absence of ongoing rehabilitation programmes may exacerbate these patients' level of handicap. This may in turn increase the financial burden on the health care system. Home-based rehabilitation programmes are one way of providing ongoing low-cost programmes able to maintain or even improve the performance of these patients.

Transcutaneous electrical nerve stimulation (TENS) to the common peroneal nerve reduces spasticity and the hyperactive stretch reflex of ankle plantarflexors and improves dorsiflexor strength in patients with chronic stroke.[1] Repetitive electrical stimulation of the hemiparetic forearm extensor muscle leads to reorganisation in both the somatosensory and primary motor cortex. We hypothesised that combining TENS-induced afferent signals with the cortical motor command signals generated during task-related training (TRT) might induce a greater summative benefit than either intervention alone. The objective of the present study was to compare the effectiveness of three active home-based treatment programmes (TENS, TENS+TRT, and placebo-TENS with TRT [PLBO+TRT]) versus no active treatment on spasticity, muscle strength and walking performance in chronic stroke patients.

Methods

This study was conducted from January 2004 to January 2006.

Study design

We used a single-blinded, randomised, placebo-controlled trial to test our hypothesis. After giving their informed consent, subjects were allocated randomly, using a computer program, to one of four groups, receiving TENS, TENS+TRT, PLBO+TRT, or no active treatment (control). The ethics committee of our institution approved the study.

Sample size

According to a meta-analysis,[2] the minimal effect size for TENS in motor recovery of stroke subjects was 0.38, and therefore a sample of 80 subjects was necessary to achieve an 80% likelihood (β=0.2) of detecting a 20% difference (α=0.05) in improvements among the four treatment groups. The sample size was increased from 80 to 109 to account for possible dropouts.

Subjects were included if they had sustained a single stroke more than 1 year previously, were able to walk 10 m unassisted, with or without walking aids, and had a Composite Spasticity Score of ≥10 in their ankle plantarflexors. Exclusion criteria were medical comorbidity, eg unstable cardiopulmonary disease (acute myocardial infarction, wearing a cardiac pacemaker, shortness of breath, tachycardia), uncontrolled diabetes mellitus, or pre-existing neurological disorders such as multiple sclerosis, receptive dysphasia, or cognitive impairment (denoted by scoring <7 out of 10 on the Abbreviated Mental Test).

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Department of Rehabilitation Sciences, The Hong Kong Polytechnic University
CWY Hui-Chan, SSM Ng, MKY Mak

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Principal applicant and corresponding author:
Prof Christina WY Hui-Chan
Department of Rehabilitation Sciences, The Hong Kong Polytechnic University, Hung Hom, Kowloon, Hong Kong SAR, China
Tel: (852) 2766 6703
Fax: (852) 2774 5131
E-mail: rschris@inet.polyu.edu.hk

Intervention

Subjects were required to perform the home rehabilitation programme daily, 5 days a week for 4 weeks. The treatment compliance and safety of the programme was closely monitored by the physiotherapist-in-charge.

The control group received no treatment. The TENS group received 60 minutes of TENS from a TENS stimulator. Electrodes were placed over four acupuncture points on the affected leg, namely ST 36 (*Zusanli*), LV 3 (*Taichong*), GB 34 (*Yanglinquan*), and UB 60 (*Kunlun*). The PLBO+TRT group received 60 minutes of placebo-TENS from TENS devices with the electrical circuit disconnected inside, followed by 60 minutes of TRT as described below.

The TENS+TRT group received 60 minutes of TENS followed by 60 minutes of TRT which included six exercises: (1) loading exercise on the affected leg, (2) stepping up exercise with the affected leg, (3) stepping down exercise with the unaffected leg, (4) heel lifts from a dorsiflexed position when standing, (5) standing up from a chair, walking a short distance, and returning to the chair, and (6) walking with rhythmic auditory cues generated by a metronome. The physiotherapist oversaw standardised progression.

Outcome measurements

An assessor blinded to the treatment allocation assessed the subjects at four time intervals: before and after 2 and 4 weeks of treatment, and 4 weeks after treatment. The five measurements have been described in our previous study, with high intraclass correlation values ranging from 0.85 to 0.99.[3] (1) Ankle plantarflexor spasticity was measured by the Composite Spasticity Scale.[4] (2) Maximum isometric voluntary contraction of the ankle muscles of both affected ankle dorsiflexors (tibialis anterior) and plantarflexors (medial gastrocnemius) was recorded using surface electromyography and torque measurements. (3) Gait velocity was measured with a 4.6-m-long instrumented carpet. (4) Walking endurance was calculated by measuring the distance covered in the 6-minute walk test. (5) Functional mobility was calculated by measuring the time taken to complete the timed 'up and go' (TUG) test.

Statistics

An intention-to-treat analysis was used. Differences in the scores from all outcome measures, obtained by subtracting pre-treatment scores from post-treatment scores, were analysed with the analysis of variance using the Statistical Package for the Social Sciences (Windows version 11.5; SPSS Inc, Chicago [IL], US), followed by post-hoc tests. The significance level was set at 5%. P values were corrected using the Bonferroni adjustment.

Results

A total of 109 subjects, with a mean age of 56.6±7.9 years and mean post-stroke period of 4.7±3.4 years, were included. Eight (7.3 %) subjects dropped out from the study. No significant differences were found between the groups in the five baseline outcome measurements (age, gender, weight, height, and the type, side and duration of their strokes).

Each of the three treatment groups showed better overall improvements than the control group. Among the treatment groups, combining TENS with TRT was superior to the other interventions for improving motor functions. When compared with the TENS group, only patients of the combined TENS+TRT group maintained their increase in ankle dorsiflexion torque at 4 weeks after treatment (Table 2), and showed significantly greater increases in ankle plantarflexion torque at week 2 and at 4 weeks after treatment (Table 2), greater increases in the distance covered during the 6-minute walk test (Table 3), and greater decreases in their TUG scores from week 2 onwards (Table 3). When compared with the PLBO+TRT group, only patients of the combined TENS+TRT group demonstrated earlier and significantly greater reduction of their plantarflexor spasticity (Table 1), and greater increases in their ankle dorsiflexion torque after 2 weeks of treatment (Table 2). Only patients of the combined TENS+TRT group showed significantly greater improvements in their gait velocity (Table 3) and greater decreases in their TUG scores from week 2 onwards when compared with the other 3 groups (Table 3).

Discussion

Transcutaneous electrical nerve stimulation and motor recovery

The improvement of motor functions in the TENS group was consistent with the results from our previous study where TENS electrodes were applied over the peroneal nerve instead of acupuncture points.[1] In the present study, TENS electrodes were applied to the acupuncture points, which are all subcutaneous and close to the nerves (ie peroneal nerve) and blood vessels, hence the peroneal nerve was probably stimulated.

The TENS group had a decrease in ankle dorsiflexion torque 4 weeks after treatment (12.6 Nm; Table 2), when compared with that of week 4 (19.7 Nm; Table 2). The increase in dorsiflexion torque was maintained in the PLBO+TRT group 4 weeks after treatment. This result implies that the effects of TENS itself cannot be maintained when treatment ends and that patients with chronic stroke may need physical training to maintain the gain in muscle strength.

Task-related training and motor recovery

Spasticity did not increase after a short-term exercise programme. Instead, there was a decrease in Composite Spasticity Scale in both exercise (TENS+TRT and PLBO+TRT) groups. Our TRT programme took into account the specificity of training principles, ensuring that the force generated by the lower limb muscles was directly related to

Table 1. Composite Spasticity Scale scores before treatment (T_0), at 2 and 4 weeks of treatment (T_2 and T_3), and at 4 weeks post-treatment (T_{FU}) for the control, transcutaneous electrical nerve stimulation (TENS), TENS with task-related training (TENS+TRT), and placebo-TENS with TRT (PLBO+TRT) groups

Composite Spasticity Scale scores	Control (n=29)	TENS (n=28)	TENS+TRT (n=27)	PLBO+TRT (n=25)
Mean±SD T_0 score	11.8±1.6	12.2±1.9	12.2±1.7	12.7±1.6
Mean±SD T_2 score	11.7±1.6	11.4±1.8	11.4±1.6	12.2±1.6
$(T_2-T_0)/T_0$ (%)	-1.0*	-6.8†‡§	-6.3†‡§	-3.7†
Mean±SD T_3 score	11.6±1.5	11.1±1.8	11.2±1.4	11.5±1.7
$(T_3-T_0)/T_0$ (%)	-1.0*	-9.6†‡	-8.3†‡	-9.4†‡
Mean±SD T_{FU} score	11.7±1.6	11.6±1.9	11.4±1.6	11.7±1.6
$(T_{FU}-T_0)/T_0$ (%)	-0.7	-5.3†‡	-6.4†‡	-7.5†‡

* Within group: P<0.0 when T_2, T_3 and T_{FU} are compared with T_0
† Within group: P<0.01 when T_2, T_3 and T_{FU} are compared with T_0
‡ Among groups: P<0.01 when compared with control group
§ Among groups: P<0.05 when compared with PLBO+TRT group

Table 2. Peak torques generated by maximum isometric voluntary contraction of the affected ankle muscles before treatment (T_0), at 2 and 4 weeks of treatment (T_2 and T_3), and at 4 weeks post-treatment (T_{FU}) of the control, transcutaneous electrical nerve stimulation (TENS), TENS with task-related training (TENS+TRT), and placebo-TENS with TRT (PLBO+TRT) groups

Peak torques	Control (n=29)	TENS (n=28)	TENS+TRT (n=27)	PLBO+TRT (n=25)
Dorsiflexion				
Mean±SD T_0 (Nm)	13.0±8.1	12.8±6.9	11.6±5.3	9.6±5.4
Mean±SD T_2 (Nm)	14.1±8.9	16.7±6.8	15.2±5.9	11.1±5.9
$(T_2-T_0)/T_0$ (%)	5.8	38.2*†‡	39.8*†‡	15.9*
Mean±SD T_3 (Nm)	14.3±8.4	19.7±6.9	17.3±5.0	13.9±5.8
$(T_3-T_0)/T_0$ (%)	10.4*	67.1*†	72.4*†	57.0*†
Mean±SD T_{FU} (Nm)	14.3±8.5	14.2±6.6	16.9±5.6	13.9±6.1
$(T_{FU}-T_0)/T_0$ (%)	9.2	12.6‡§	65.6*†‖	57.8*†
Plantarflexion				
Mean±SD T_0 (Nm)	16.6±10.9	16.0±9.3	17.4±6.8	12.9±5.9
Mean±SD T_2 (Nm)	16.1±10.3	17.1±9.9	20.3±7.3	14.6±7.2
$(T_2-T_0)/T_0$ (%)	-0.4	7.6*	19.4*†¶	13.9*†
Mean±SD T_3 (Nm)	16.9±9.9	19.2±10.0	23.5±8.0	19.7±14.4
$(T_3-T_0)/T_0$ (%)	7.2	22.7*	42.9*	70.5
Mean±SD T_{FU} (Nm)	17.8±11.1	17.8±9.4	22.8±8.4	16.3±7.3
$(T_{FU}-T_0)/T_0$ (%)	11.6*	15.2*	34.6*†‖	30.3**

* Within group: P<0.01 when T_2, T_3 and T_{FU} are compared with T_0
† Among groups: P<0.01 when compared with control group
‡ Among groups: P<0.01 when compared with PLBO+TRT group
§ Within group: P<0.05 when T_2, T_3 and T_{FU} are compared with T_0
‖ Among groups: P<0.01 when compared with TENS group
¶ Among groups: P<0.05 when compared with TENS group
** Among groups: P<0.05 when compared with control group

gait performance. Although the exclusive effect of TRT was not delineated in the present study, placebo stimulation of the lower limb has negligible effects on clinical spasticity and ankle muscle strength in subjects with chronic stroke.[1]

As our programme involved repetitive strengthening of the plantarflexors, only the subjects in the exercise (TENS+TRT and PLBO+TRT) groups (not those in the TENS group) demonstrated an improvement in plantarflexor strength. The physiological mechanisms underlying strength gains in the post-stroke population is an area that warrants further study.

The percentage increases in the distances covered during the 6-minute walk test after the gait training programme (20.2% to 28.01%) reported in previous studies were comparable with those shown by our two exercise (TENS+TRT and PLBO+TRT) groups (29.3% and 17.7%, respectively) but not the TENS group (9.1%). It appears that task-related exercises play a major role in mediating the increase in 6-minute walk distance in both exercise groups.

Combining transcutaneous electrical nerve stimulation with task-related training

As increased motor-evoked potentials in the tibialis anterior were maintained for 110 minutes following 30 minutes of stimulation over the common peroneal nerve,[5] we expected that subjects would gain most benefit if they practised TRT following repetitive electrical stimulation when cortical excitability should be increased. This is why we asked subjects to practise TRT after (rather than during) the 60-minute electrical stimulation session.

The two exercise groups showed increased ankle dorsiflexion torque, with the improvement occurring 2 weeks earlier in the combined TENS+TRT group. As TENS was found to reduce plantarflexor spasticity and increase dorsiflexion torque,[1] the addition of TENS to TRT may have enabled patients to make extra efforts during the earlier phase of training, thereby achieving earlier improvements

Table 3. Gait velocity, distance covered in the 6-minute walk test, and scores of the timed 'up and go' test before treatment (T_0), at 2 and 4 weeks of treatment (T_2 and T_3), and at 4 weeks post-treatment (T_{FU}) of the control, transcutaneous electrical nerve stimulation (TENS), TENS with task-related training (TENS+TRT), and placebo-TENS with TRT (PLBO+TRT) groups

Tests	Control (n=29)	TENS (n=28)	TENS+TRT (n=27)	PLBO+TRT (n=25)
Gait velocity				
Mean±SD T_0 (cm/s)	58.9±24.9	57.7±26.3	47.9±26.8	50.7±24.5
Mean±SD T_2 (cm/s)	59.6±26.1	60.8±27.4	63.2±32.2	56.2±27.0
$(T_2-T_0)/T_0$ (%)	0.004	6.6*	37.1†‡§‖	12.1†
Mean±SD T_3 (cm/s)	60.9±24.8	64.9±28.9	66.6±32.5	60.6±29.7
$(T_3-T_0)/T_0$ (%)	4.3	14.3†	47.4†‡§‖	19.6†
Mean±SD T_{FU} (cm/s)	61.2±24.2	61.2±27.3	70.2±32.7	61.3±28.6
$(T_{FU}-T_0)/T_0$ (%)	5.4	7.7†	57.5†‡§‖	22.1†
Distance covered in 6-minute walk test				
Mean±SD T_0 (m)	195.6±75.9	202.6±81.8	191.9±89.4	175.9±81.9
Mean±SD T_2 (m)	194.2±70.9	205.5±83.9	225.0±92.6	194.7±91.9
$(T_2-T_0)/T_0$ (%)	1.1	1.6	22.2†‡‖	10.7†
Mean±SD T_3 (m)	196.2±70.7	221.0±90.6	242.0±104.1	206.7±97.2
$(T_3-T_0)/T_0$ (%)	2.6	9.1*	29.3†‡‖	17.7†‡
Mean±SD T_{FU} (m)	197.9±68.6	219.3±92.8	245.5±99.7	206.82±85.8
$(T_{FU}-T_0)/T_0$ (%)	3.8	7.8*	34.7†‡‖	20.2†¶
Scores of timed 'up and go' test				
Mean±SD T_0 (s)	22.9±13.5	22.7±10.9	25.5±17.4	29.4±22.1
Mean±SD T_2 (s)	23.2±14.9	21.4±10.6	20.9±12.4	27.8±22.8
$(T_2-T_0)/T_0$ (%)	-0.6	-6.1†	-14.9†‡§‖	-6.3†
Mean±SD T_3 (s)	22.9±13.2	20.6±10.4	18.7±9.7	26.2±21.7
$(T_3-T_0)/T_0$ (%)	0.7	-10.4†‡	-21.7†‡§‖	-12.1†‡
Mean±SD T_{FU} (s)	22.2±12.5	21.0±9.9	18.8±11.2	25.3±19.7
$(T_{FU}-T_0)/T_0$ (%)	-1.7	-7.2†††	-23.3†‡‖**	-14.9†‡

* Within group: P<0.05 when T_2, T_3 and T_{FU} are compared with T_0
† Within group: P<0.01 when T_2, T_3 and T_{FU} are compared with T_0
‡ Among groups: P<0.01 when compared with control group
§ Among groups: P<0.01 when compared with PLBO+TRT group
‖ Among groups: P<0.01 when compared with TENS group
¶ Among groups: P<0.05, when compared with control group
** Among groups: P<0.05 when compared with PLBO+TRT group

in peak torques.

In our study, gait velocity was improved by 14.3%, 19.6 % and 47.4 %, respectively, in the TENS, PLBO+TRT and TENS+TRT groups (Table 3). These results support our hypothesis that combining TENS with TRT would augment motor recovery more than either TENS or PLBO+TRT alone, even in subjects whose strokes had occurred 4.3 to 5.0 years previously.

After 4 weeks of treatment, patients of the combined TENS+TRT group shortened the TUG by 21.7%. This was significantly greater than that in the TENS (10.4 %) and PLBO+TRT (12.1 %) groups. This improvement in TUG scores had clinical significance. After 4 weeks of treatment, only patients in the combined TENS+TRT group could finish the task in less than 20 seconds. Patients able to complete the TUG in 20 seconds were considered independent in the transfer tasks involved in activities of daily living.[6] Clearly, TENS has the potential to become a useful complementary therapy in a home-based TRT.

This study has certain limitations. First, not all subjects were blinded to their treatment, because the two exercise groups were aware that they were receiving exercise intervention. Moreover, subjects in the control group participated in four assessment sessions only, so the frequency of therapist-patient contacts was less than that for the three treatment groups. Due to resource limitation, treatment effectiveness was examined for only 4 weeks after treatment. Whether greater improvements can be attained if treatment duration is extended remains unknown.

Conclusion

Home-based rehabilitation programmes improved the lower limb motor functions in patients who had sustained strokes more than 1 year previously. A combination of TENS with TRT decreased plantarflexor spasticity, improved ankle dorsiflexor and plantarflexor strength, and increased gait velocity significantly more than either TENS alone, PLBO+TRT, or no treatment.[7] Most of these improvements were maintained 4 weeks after treatment.

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