Background and Purpose—Previous studies have shown that repeated sensory inputs could enhance brain plasticity and cortical motor output. The purpose of this study was to investigate whether combining electrically induced sensory inputs through transcutaneous electrical nerve stimulation (TENS) with task-related training (TRT) in a home-based program would augment voluntary motor output in chronic stroke survivors better than either treatment alone or no treatment.

Methods—Eighty-eight patients with stroke were assigned randomly to receive a home-based program of (1) TENS, (2) TENS + TRT, (3) placebo TENS + TRT, or (4) no treatment (control) 5 days a week for 4 weeks. Outcome measurements included Composite Spasticity Scale, peak torques generated during maximum isometric voluntary contraction of ankle dorsiflexors and plantarflexors, and gait velocity recorded at baseline, after 2 and 4 weeks of treatment, and 4 weeks after treatment ended.

Results—When compared with TENS, the combined TENS + TRT group showed significantly greater improvement in ankle dorsiflexion torque at follow-up and in ankle plantarflexion torque at week 2 and follow-up (P < 0.01). When compared with placebo + TRT, the TENS + TRT group produced earlier and greater reduction of plantarflexor spasticity and improvement in ankle dorsiflexion torque at week 2 (P < 0.01). When compared with all 3 groups, the TENS + TRT group showed significantly greater improvement in gait velocity (P < 0.01).

Conclusions—In patients with chronic stroke, 20 sessions of a combined TENS + TRT home-based program decreased plantarflexor spasticity, improved dorsiflexor and plantarflexor strength, and increased gait velocity significantly more than TENS alone, placebo + TRT, or no treatment. Such improvements can even be maintained 4 weeks after treatment ended. (Stroke. 2007;38;2953-2959.)

Key Words: rehabilitation stroke transcutaneous electrical nerve stimulation
motor performance together with somatosensory evoked potential normality classification of the paretic limbs.

Task-related training (TRT) is a rehabilitation strategy that involves the practice of goal-directed, functional movements in a natural environment to help patients derive optimal control strategies for alleviating movement disorders. In a TRT program, the patient is required to work in a task-specific or self-driven or goal-driven activity while being put in a position in which the weakened muscle would normally function. Studies with stroke populations have shown that TRT with specific strengthening exercises for paretic muscles improve locomotion, lower limb weightbearing in sitting, and standing up. Recent studies using functional MRI and optical imaging system demonstrated that lower limb TRT induces use-dependent plastic changes of brains in patients with stroke. Thus, TRT is expected to promote recovery of lower limb functions in hemiparetic patients.

Our previous study showed that TENS excites large-diameter Aβ afferents, which would include sensory and motor fibers. Because increased sensory input could facilitate cortical synaptic reorganization and motor output, we hypothesized that combining TENS with TRT would induce a greater summative benefit than either intervention alone. The objective of present study was to compare the effectiveness of 3 active home-based treatment programs (TENS, TENS+TRT, and placebo-TENS+TRT) versus no active treatment on spasticity, muscle strength, and functional ability (ie, walking) in patients with chronic stroke.

Materials and Methods

Study Design

This is a single-blinded, stratified, randomized, controlled trial. According to a meta-analysis, the minimal effect size for TENS in motor recovery of stroke subjects was 0.38. A sample of 80 subjects was necessary to achieve 80% chance (β level=0.2) of detecting 20% difference (α level=0.05) in improvements among the 4 treatment groups. Anticipating possible dropout, the sample size was increased to 88.

Randomization

Having given informed consent, subjects were allocated by a random number produced by Jensen’s computer program called “Mini-mize” to one of 4 groups receiving TENS, TENS+TRT, placebo-TENS (PLBO) with TRT, or no treatment (control). Randomization was carried out after stratification of known variables, which included age (45 to 59 and 60 to 74 years), gender (male and female), type of stroke (cerebral ischemia and hemorrhage), side of hemiplegia (left and right), and level of plantarflexor spasticity (moderate and severe, assessed by the Composite Spasticity Scale).

Subjects

Eighty-eight subjects, 57.3±8.1 years old and 5.3±3.5 years after stroke, were recruited from the community rehabilitation network (Figure 1). Subjects were included if they had a single stroke at least 1 year ago, 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, receptive dysphasia, or cognitive impairment denoted by scoring <7 of 10 on the Abbreviated Mental Test.

Intervention

Subjects were required to perform the home program daily 5 days a week for 4 weeks. During this period, they attended 8 instruction sessions in our laboratory to ensure that they could follow the home program properly and for the physiotherapist to progress the exercise level as needed. Daily log books were entered by all subjects. To ensure treatment compliance, the physiotherapist made regular telephone reminders and checked clients’ daily log books in every instruction session.

The control group received no treatment. The TENS group received 60 minutes of TENS (100 Hz, 0.2-ms square pulses, 2 to 3 times sensory threshold) from a TENS stimulator (CEFAR Dumo 2.4 K; Cefar Medical Products AB, Lund, Sweden). Electrodes were placed over 4 acupuncture points of the affected leg, namely ST 36 (Zusanli), LV 3 (Taichong), GB 34 (Yanglingquan), and UB 60 (Kunlun). These acupoints were selected according to traditional Chinese medicine and a previous stroke study. The PLBO+TRT group received 60 minutes of PLBO-TENS from identical-looking TENS devices with the electrical circuit disconnected inside followed by 60 minutes of TENS as described subsequently.

The TENS+TRT group received 60 minutes of TENS followed by 60 minutes of TRT modified from Carr and Shepherd. TRT included 4 weightbearing and stepping exercises using wooden blocks of 2.5 or 5 cm in height: (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 in standing and 2 functional training; (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. Standardized progression was made by the physiotherapist by using higher wooden blocks when subjects could perform the weightbearing exercises 20 times without compensatory movement and by increasing the number of repetitions completed within 10 minutes. Walking was progressed by increasing its speed.

Outcome Measurements

To eliminate possible bias during measurements, subjects were assessed by an assessor blinded to treatment allocation at 4 time intervals: before and after 2 and 4 weeks of treatment and follow-up at 4 weeks after treatment.

Ankle plantarflexor spasticity was measured by the Composite Spasticity Scale developed by Chan, which has been shown to be reliable and valid in people with stroke. Peak torques of maximum isometric voluntary contraction of ankle dorsiflexors and plantarflexors were recorded with a load cell mounted on a custom-built foot frame while subjects lay supine with knee and ankle kept at 50° of flexion and in neutral position, respectively. Gait velocity was measured with a 4.6-m long instrumented carpet (GAITRite). During testing, subjects walked with their comfortable footwear at a normal speed and gait velocity was calculated by GAITRite software (version 2.2). All measurement protocols had been tested for reproducibility in our previous study, which showed high intraclass correlation coefficient values ranging from 0.85 to 0.99.

Statistics

Descriptive statistics were used for relevant subject characteristics. Differences in scores of all outcome measures, obtained by subtracting pretreatment scores from posttreatment scores, were analyzed with repeated measures of analysis of variance using SPSS (version 11.5) followed by post hoc tests. The between-subjects factor was the “4 groups” and the within-subject factor was the “4 time intervals.” Significance level was set at 5%. Probability values were corrected by a method suggested by Benjamini and Hochberg because it is not as conservative as Bonferroni adjustment but still maintains the overall type I error at 5%.

Results

Figure 1 showed that 88 subjects with chronic stroke who met the inclusion criteria participated in the study. Eight subjects (9.0%) dropped out: 2 from the control group, 3 from the TENS group, 2 from the PLBO+TRT group, and one from...
the TENS+TRT group. No significant differences were found in the baseline values among groups (Tables 1 and 2).

**Composite Spasticity Scale**
All 3 intervention groups showed a significantly greater amount and percentage of reduction in plantarflexor spasticity when compared with the control group at week 4 ($P<0.01$; Table 2A; Figure 2A) with improvements maintained at follow-up. When compared with the PLBO+TRT group, both TENS (TENS and TENS+TRT) groups showed earlier and significantly greater of reduction in plantarflexor spasticity as measured by the Composite Spasticity Scale at week 2 ($P<0.01$).

**Maximum Isometric Voluntary Contraction**
All 3 intervention groups showed a significantly greater amount and percentage of increase in dorsiflexion torque when compared with the control group at week 4 ($P<0.01$; Table 2B; Figure 2B). When compared with the PLBO+TRT and control groups, both TENS (TENS and TENS+TRT) groups showed earlier and significantly greater improvement in peak ankle dorsiflexion torque at week 2 ($P<0.01$). Interestingly, at follow-up, only the 2 exercise (PLBO+TRT and TENS+TRT) groups maintained significant percentage increase in peak ankle dorsiflexion torque when compared with TENS and control groups ($P<0.01$).

When compared with the control group, the 2 exercise (TENS+TRT and PLBO+TRT) groups showed a signifi-
cantly greater percentage increases in peak plantarflexion torques from week 2 onward ($P<0.05$; Figure 2C). However, when compared with the TENS group, only the combined TENS+TRT group showed a significantly greater amount and percentage of improvement in peak ankle plantarflexion torque at week 2 and at follow-up ($P<0.01$; Table 2C; Figure 2C).

**Gait Velocity**

Only the combined TENS+TRT group showed a significantly greater amount and percentage increase in gait velocity when compared with the TENS, PLBO+TRT, and control groups at week 2 and at week 4 ($P<0.01$; Table 2D; Figure 2D). Such improvements can even be maintained at follow-up.

**Discussion**

This study demonstrates that combining TENS with TRT was more superior to the other interventions in improving motor functions in subjects with chronic stroke. First, when compared with the TENS group, only the combined TENS+TRT

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**Table 1. Subject Characteristics for Each Treatment Group**

<table>
<thead>
<tr>
<th></th>
<th>Control (n=20)</th>
<th>TENS (n=19)</th>
<th>PLBO+TRT (n=20)</th>
<th>TENS+TRT (n=21)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>57.3±8.6</td>
<td>56.4±9.1</td>
<td>57.1±7.8</td>
<td>58.4±7.1</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male, %</td>
<td>17 (85.0)</td>
<td>17 (89.5)</td>
<td>17 (85.0)</td>
<td>16 (76.2)</td>
</tr>
<tr>
<td>Female, %</td>
<td>3 (15.0)</td>
<td>2 (15.0)</td>
<td>3 (15.0)</td>
<td>5 (23.8)</td>
</tr>
<tr>
<td>Paretic side</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left, %</td>
<td>13 (65.0)</td>
<td>10 (52.6)</td>
<td>10 (50.0)</td>
<td>14 (66.7)</td>
</tr>
<tr>
<td>Right, %</td>
<td>7 (35.0)</td>
<td>9 (47.4)</td>
<td>10 (50.0)</td>
<td>7 (33.3)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>23.6±6.0</td>
<td>25.8±2.6</td>
<td>24.4±3.8</td>
<td>24.9±3.0</td>
</tr>
<tr>
<td>Composite Spasticity Scale score</td>
<td>11.7±1.6</td>
<td>12.2±1.7</td>
<td>12.1±1.6</td>
<td>12.2±1.7</td>
</tr>
<tr>
<td>Years since first stroke</td>
<td>5.2±2.9</td>
<td>6.2±4.1</td>
<td>4.7±4.1</td>
<td>5.0±3.0</td>
</tr>
</tbody>
</table>

Values are mean±SD.

---

**Table 2. Comparison of Outcome Measurements Among the 3 Groups**

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>TENS</th>
<th>PLBO+TRT</th>
<th>TENS+TRT</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Composite Spasticity Scale</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline, mean±SD</td>
<td>11.8±1.7</td>
<td>12.2±1.7</td>
<td>12.2±1.5</td>
<td>12.1±1.7</td>
</tr>
<tr>
<td>Week 2</td>
<td>11.7±1.7</td>
<td>11.4±1.7§</td>
<td>11.9±1.5</td>
<td>11.3±1.6§</td>
</tr>
<tr>
<td>Week 4</td>
<td>11.6±1.6</td>
<td>11.0±1.7§</td>
<td>11.2±1.7§</td>
<td>11.0±1.4§</td>
</tr>
<tr>
<td>Follow-up</td>
<td>11.7±1.6</td>
<td>11.5±1.7§</td>
<td>11.4±1.5§</td>
<td>11.2±1.5§</td>
</tr>
<tr>
<td>Peak torque, Nm</td>
<td>13.9±8.9</td>
<td>13.2±8.0</td>
<td>10.3±5.8</td>
<td>11.3±4.8</td>
</tr>
<tr>
<td>B. Dorsiflexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline, mean±SD</td>
<td>15.1±9.6</td>
<td>16.9±7.8§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Week 2</td>
<td>15.2±9.0</td>
<td>19.8±8.1§</td>
<td>14.7±6.2§</td>
<td>16.9±4.8§</td>
</tr>
<tr>
<td>Week 4</td>
<td>15.0±9.2</td>
<td>14.7±7.4</td>
<td></td>
<td>14.7±6.5§</td>
</tr>
<tr>
<td>Follow-up</td>
<td>17.8±11.5</td>
<td>16.4±10.8</td>
<td>12.8±6.7</td>
<td>17.5±7.0</td>
</tr>
<tr>
<td>C. Plantarflexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline, mean±SD</td>
<td>17.5±11.3</td>
<td>17.6±11.6</td>
<td>14.4±8.0‡</td>
<td>20.7±7.5¶</td>
</tr>
<tr>
<td>Week 2</td>
<td>18.3±10.5</td>
<td>19.5±11.5</td>
<td>20.3±16.0¶</td>
<td>23.8±8.5¶</td>
</tr>
<tr>
<td>Week 4</td>
<td>19.0±11.8</td>
<td>18.1±10.8</td>
<td>16.1±8.0¶</td>
<td>22.7±8.4¶</td>
</tr>
<tr>
<td>Follow-up</td>
<td>62.6±24.6</td>
<td>54.8±25.6</td>
<td>48.7±25.0</td>
<td>50.6±28.3</td>
</tr>
<tr>
<td>D. Gait velocity, cm/s</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline, mean±SD</td>
<td>63.2±25.8</td>
<td>58.1±27.1</td>
<td>53.9±27.8</td>
<td>64.9±34.0¶</td>
</tr>
<tr>
<td>Week 2</td>
<td>63.9±24.1</td>
<td>62.9±28.4</td>
<td>57.7±29.8</td>
<td>68.2±34.5¶</td>
</tr>
<tr>
<td>Week 4</td>
<td>64.5±23.8</td>
<td>58.8±26.5</td>
<td>58.3±28.8</td>
<td>72.2±34.0¶</td>
</tr>
</tbody>
</table>

Comparisons of all outcome measures were analyzed with repeated measures of analysis of variance using changes in raw data from baseline values.

Within group: *$P<0.05$, †$P<0.01$ when compared with baseline values.

Among groups: ‡$P<0.05$, §$P<0.01$ when compared with the control group; †$P<0.01$ when compared with the PLBO + TRT group; ¶$P<0.01$ when compared with the TENS group.
group maintained the increase in ankle dorsiflexion torque at follow-up and showed a significantly greater increase in ankle plantarflexion torque at week 2 and at follow-up. Second, when compared with the PLBO/H11001 TRT group, only the combined TENS/H11001 TRT group demonstrated earlier and greater reduction of plantarflexor spasticity and increase in ankle dorsiflexion torque after 2 weeks of treatment. Third, only the combined TENS/H11001 TRT group showed significantly greater improvement in gait velocity from week 2 onward when compared with the other 3 groups.

Transcutaneous Electrical Nerve Stimulation on Motor Recovery

Similar to our previous findings when TENS was applied over the peroneal nerve,1 results of our present study showed that TENS to acupoints decreased plantarflexor spasticity and enhanced dorsiflexor force production in patients with chronic stroke. Possible mechanisms underlying the improvements could be attributable to an enhancement of presynaptic inhibition of the hyperactive stretch reflexes in spastic muscles, decrease in the cocontraction of spastic antagonists, and disinhibition of descending voluntary commands to the motoneurons of paretic muscles as suggested.1 Note that TENS electrodes were applied to the acupuncture points located on the anterolateral aspect of the affected lower limb, which are subcutaneous and close to the nerves (ie, peroneal nerve) and blood vessels. The areas covered by the TENS electrodes were much bigger than those of acupuncture points and probably excited the areas innervated by the peroneal nerve.

Our results contrasted with those of Johansson and colleagues,28 which showed that 20 sessions of TENS to acupuncture points over a 10-week period had no beneficial effects in patients days 5 to 10 after acute stroke. Such differences in the findings could be attributed to differences in the length of time since stroke and/or treatment intensity. Besides, their measurement tools28 were mainly clinical scales such as Barthel Index and Rivermead Mobility Index, which may not be sensitive and/or specific enough to detect changes in spasticity and muscle strength.

The carryover effect of high-frequency TENS on muscle strength in patients with chronic stroke had not been addressed in previous studies. Our findings showed a decrease in ankle dorsiflexion torque 4 weeks after treatment ended at follow-up (14.7 Nm; Table 2B) when compared with that of week 4 (19.8) in the TENS group. This result implies that effects of TENS itself cannot be maintained when treatment ended and that physical training maybe needed to maintain the gain in muscle strength. This speculation is now supported by our finding that the increase in dorsiflexion torque was maintained by the PLBO+TRT group at follow-up.

It could be argued that because subjects receiving PLBO-TENS did not feel anything, they knew they were not stimulated. However, we had kept a constant mental set at the study onset by informing all subjects that they might or might...
not feel any stimulation. Even when subliminal electrical stimulation was used, it would be difficult to rule out any brain activation, because study with functional MRI has demonstrated that whole-hand stimulation at a subthreshold level for sensation could still affect regional blood flow in the primary and secondary motor and somatosensory areas of the brain.

Task-Related Training on Motor Recovery
Our TRT program took into account the specificity of training principles by ensuring that the force generated by the muscles is directly related to gait performance. Although the exclusive effects of TRT had not been delineated in the present study, Levin and Hui-Chan1 had already shown that placebo stimulation on the lower extremity produced negligible effects on clinical spasticity and ankle muscle strength in chronic stroke subjects. If their findings could be generalized to the present stroke population, then the improvements manifested by the PLBO+TRT group may be largely attributable to TRT alone.

One may question why the percentage increase in ankle dorsiflexion torque (54.0 in PLBO+TRT and 68.5 in TENS+TRT) at week 4 was consistently greater than that of plantarflexion torque (34.5 in PLBO+TRT and 42.3 in TENS+TRT; Figure 2B and 2C) in both exercises (TENS+TRT and PLBO+TRT) groups. Such a discrepancy could be attributed to the differential effect of knee position on ankle dorsiflexors and plantarflexors during assessment. In our study, ankle muscle strength was assessed with the knee flexed at 50°. Knee flexion will place less stretch on the gastrocnemius (plantarflexor) but not the dorsiflexor; hence, it will decrease the net force generated by the plantarflexor.

Our results are consistent with those of previous studies showing that spasticity decreased, instead of increased, after a short-term exercise program.29,30 Because our exercise program involved repetitive strengthening of the plantarflexors, it is not surprising to note that only the subjects in both TRT (TENS+TRT and PLBO+TRT) groups, but not those in the TENS group, demonstrated improvement in plantarflexor strength. The mechanisms underlying improvements in muscle strength appear multifactorial and could be attributed to enhancement of descending voluntary commands to the paretic muscles,13,32 reduced agonist-antagonist cocontraction,1 and reorganization of synapses and cortical representation after repetitive practice of functional tasks.16,17,33 The physiological mechanisms underlying strength gains in the stroke population is an area that warrants further study.

Consistent with previous studies11,34 showing the effects of 4- to 6-week TRT programs on patients with stroke, the intensity of our 4-week program was sufficient to produce improvements of motor functions. Greater improvements may be possible with a longer period of training. Regrettfully, investigation of the optimal dosage of the training program in terms of frequency, duration, and intensity is beyond the scope of the present clinical trial. Note that patients’ active participation could be a key reason for the 2 exercise (TENS+TRT and PLBO+TRT) groups to maintain the improvement in muscle strength at follow-up, because most subjects in these groups continued to practice the exercise on their own even after treatment ended.

Combining Transcutaneous Electrical Nerve Stimulation With Task-Related Training
Because increased motor evoked potentials of the tibialis anterior were found to be maintained for at least 110 minutes after 30 minutes of stimulation over the common peroneal nerve in 10 healthy subjects,35 we purported that subjects would gain the most benefits if they practiced TRT after repetitive electrical stimulation when the cortical excitability was supposed to be increased. This is why we asked subjects to practice TRT after rather than simultaneously with the 60 minutes of electrical stimulation.

The 2 exercise (TENS+TRT and PLBO+TRT) groups showed increased ankle dorsiflexion torque with the improvement occurring 2 weeks earlier in the combined TENS+TRT group. Because TENS was found to reduce plantarflexor spasticity and increase dorsiflexing torque,1–3 the addition of TENS to TRT could have enabled patients to exert extra efforts during the earlier phase of training, thereby achieving earlier improvement in peak torques.

In our study, gait velocity was improved by 18.5% and 34.9%, respectively, in the PLBO+TRT and TENS+TRT groups (Figure 2D). Previous studies on patients with stroke have shown that 4 weeks of gait training can increase gait velocity by 13%11 to 21%,36 which was consistent with the improvement shown in our PLBO+TRT group (18.5%). These results support our hypothesis that combining TENS with TRT would augment the motor recovery more than either TENS or PLBO+TRT alone, even in subjects who had a stroke at least 1 year previously. The improvement in gait velocity found in the combined TENS+TRT group had clinical significance. All subjects in our study with gait velocity from 48.7 to 62.6 cm/s were classified as least-limited community walkers (50 to 80 cm/s) before treatment.37 After 4 weeks of combined TENS+TRT treatment, the mean gait velocity of subjects approached the value set for community walkers (≥80 cm/s), who are thought to be independent in all home and moderate community activities. Clearly, TENS could become an extremely useful complementary therapy to a home-based TRT program.

The present study has certain limitations. First, not all subjects were blinded to their “treatment,” because the 2 exercise groups were aware that they were receiving exercise intervention. Moreover, subjects in the control group participated in 4 assessment sessions only, so the frequency of therapist–patient contact was less than the 3 treatment groups. Because of resource limitations, treatment effectiveness was examined only up to 4 weeks after treatment ended. Whether greater improvements in motor functions can be attained if treatment duration is extended remains unknown. Although treatment compliance was not systematically examined, client compliance was reported to be excellent by the physiotherapist.

Conclusion
Twenty sessions of home-based programs could improve the motor function of lower limbs in patients with stroke at least 1 year ago. Of special interest are the novel findings that combining TENS with TRT decreased plantarflexor spasticity, improved dorsiflexor and plantarflexor strength, and
increased gait velocity significantly more than TENS alone, PLBO+TRT, or no treatment. Such improvements could even be maintained 4 weeks after treatment ended. These findings make TENS particularly useful as complementary therapy to a home-based TRT program for subjects with chronic stroke. Such a program has the added benefits of being cost-effective and convenient to patients with mobility impairment.

Acknowledgments
We thank the Community Rehabilitation Network for assistance in recruiting subjects.

Sources of Funding
This study was supported by the Health Service Research Fund (K-ZK34) from the Hong Kong Government (SAR) and a scholar-ship from The Hong Kong Polytechnic University to S.S.M.N.

Disclosures
None.

References


Transcutaneous Electrical Nerve Stimulation Combined With Task-Related Training Improves Lower Limb Functions in Subjects With Chronic Stroke
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Stroke. 2007;38:2953-2959; originally published online September 27, 2007;
doi: 10.1161/STROKEAHA.107.490318
Stroke is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0039-2499. Online ISSN: 1524-4628

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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