9

Lower Extremity Interventions

Evidence Tables

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Last Updated: March 2018

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# 9.1 Therapeutic Approach

## Table 9.1.1 Summary of Studies Evaluating Therapeutic Approach

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<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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<tr>
<td>Wagenaar et al. (1990)</td>
<td>Netherlands</td>
<td>PCT</td>
<td>TPS=5-9d</td>
<td>N=7</td>
<td>Patients alternated between two therapy approaches in a randomized order: Brunnstrom approach and Bobath. Therapies were provided for 30min/d for 21 weeks. Barthel Index and gait parameters were assessed.</td>
<td>The only significant difference found between the groups at the end of the treatment period was for comfortable walking speed, favouring the Brunnstrom method.</td>
</tr>
<tr>
<td>Gelber et al. (1995)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&lt;1mo</td>
<td>Patients with pure motor hemiparesis were randomized to neurodevelopmental technique (NDT; Bobath) or traditional functional retraining (TRF) treatment approaches for the period of inpatient rehabilitation. Functional Independence Measure, gait velocity, and stride length were evaluated at admission, discharge, 6 and 12 months.</td>
<td>There were no significant differences between the groups at any of the testing intervals, other than a difference in gait velocity at discharge, which favoured the NDT approach. Length of hospital stay was similar for both groups.</td>
</tr>
<tr>
<td>Dean et al. (1997)</td>
<td>Australia</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&gt;1yr</td>
<td>Patients were randomized into an experimental or control group providing 10 treatment sessions over 2 weeks. The experimental group participated in a standardized training program involving practice of reaching beyond arm’s length (motor learning approach). The control group received sham training involving completion of cognitive-manipulative tasks within arm’s length. Performance of reaching in sitting was measured before and after training using electromyography, videotaping, and two force plates. Variables tested were movement time, distance reached, vertical ground reaction forces through the feet, and muscle activity. Subjects were also tested on sit-to-stand, walking, and cognitive tasks.</td>
<td>After training, experimental subjects were able to reach faster and further, increase load through the affected foot, and increase activation of affected leg muscles compared with the control group. Neither group improved in walking.</td>
</tr>
<tr>
<td>Patel et al. (1998)</td>
<td>UK</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS=Subacute</td>
<td>Patients with moderate disability received treatment on a rehabilitation unit that was impairment-focused and theoretically-driven, or disability-focused and aimed at restoration of normal function (Bobath).</td>
<td>Both one week and discharge Barthel Index scores were similar between the two groups. Length of stay was shorter for patients who received treatment on the disability-focused rehabilitation unit, 53.7 vs. 72.3 days.</td>
</tr>
<tr>
<td>Langhammer et al. (2000)</td>
<td>Norway</td>
<td>RCT</td>
<td></td>
<td>N=184</td>
<td>Patients randomized to receive therapy based on Bobath concept (represents a theoretical framework in a reflex-hierarchical theory) or to receive a Motor Relearning Programme (MRP) based on system theory and task</td>
<td>Length of stay was significantly shorter in MRP group compared to Bobath group, 21 vs. 34 days.</td>
</tr>
<tr>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Study Description</td>
<td>Key Findings</td>
<td></td>
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<tr>
<td>8</td>
<td>Subacute</td>
<td>61</td>
<td>All patients received physiotherapy 5 days weekly with a minimum of 40 minutes duration as long as they were hospitalized. Both groups received the same comprehensive multidisciplinary treatment for stroke from doctors, nurses, occupational therapist, and speech therapist according to Norwegian recommendations.</td>
<td>Bobath method was most effective for retraining sitting symmetry after stroke in the short term. The BPM and the non-training control group also demonstrated significant improvement. After 12 weeks 83% of BMP group, 38% of task-specific group, 29% of Bobath group and 0% of controls were found to be distributing weight to both sides.</td>
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<tr>
<td>8</td>
<td>Acute</td>
<td>40</td>
<td>Patients with recent stroke and who bore the majority of their weight consistently to one side while sitting were randomized to one of 4 groups: task specific reach, Bobath method, balance performance monitor (BPM) feedback training, and control. Patients were measured on weight distribution measurements using BPM daily before treatment session, 2 weeks after cessation of treatment, and 12 weeks post study.</td>
<td>There were no clinically significant differences in measured outcome between the groups.</td>
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<tr>
<td>5</td>
<td>Subacute</td>
<td>28</td>
<td>Patients having achieved one minute of independent sitting balance, but not yet achieved 10 independent steps, were randomized to independent practice aimed at improving aspects of balance (motor learning) in addition to standard physiotherapy treatment based on the Bobath approach (n=9) or to routine care using the Bobath approach (n=19). Treatment was provided 5 days/week for 4 weeks. Proportion of patients achieving 'normal' symmetry of weight distribution during sitting, standing, rising to stand, sitting down, and reaching were assessed.</td>
<td>Following treatment patients in the intervention group had attained achieved greater improvements on the following outcomes measures: SMWT (40 m vs. 5m); comfortable walking speed (0.14 vs. 0.03 m/s); maximum walking speed (0.20 vs. 0.01 m/s); TUG (-1.2 vs. 1.7 sec).</td>
<td></td>
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<tr>
<td>8</td>
<td>&lt;1yr</td>
<td>91</td>
<td>91 community-dwelling subjects with a residual walking deficit within one year of a first or recurrent stroke were randomized to an intervention group which comprised 10 functional tasks designed to strengthen the lower extremities and enhance walking balance, speed and distance or to a control intervention focusing on upper extremity activities, 3 days a wk x 6 wks. The main outcomes assessed were 6-minute walk test (SMWT), 5-m walk (comfortable and maximum pace), Berg Balance Scale and timed ‘up and go’ test.</td>
<td>There were no differences in the proportion of patients experiencing a poor outcome. The adjusted odds ratio associated with the NDT approach was 1.7 (0.8, 3.5). There were no differences in median QoL scores between the groups at 12 months.</td>
<td></td>
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<tr>
<td>Authors</td>
<td>Country</td>
<td>Study Type</td>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Rehabilitation Approach</td>
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<tr>
<td>Van Vliet et al. (2005)</td>
<td>UK</td>
<td>RCT</td>
<td>7</td>
<td>TPS&lt;2wk</td>
<td>120</td>
<td>Bobath based (BB) or movement science based (MSB)</td>
</tr>
<tr>
<td>Wang et al. (2005)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>7</td>
<td>TPS=Acute</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>Chan et al. (2006)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>7</td>
<td>TPS&lt;1yr</td>
<td>52</td>
<td></td>
</tr>
<tr>
<td>Brock et al. (2011)</td>
<td>Australia</td>
<td>RCT</td>
<td>7</td>
<td>TPS=4-20wk</td>
<td>26</td>
<td></td>
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<tr>
<td>Chung et al. (2014)</td>
<td>China</td>
<td>Case Control</td>
<td>No Score</td>
<td>TPS=NA</td>
<td>NStart=45</td>
<td>NEnd=45</td>
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9.2 Balance Retraining

9.2.1 Balance Retraining

Table 9.2.1.1 Summary of Studies Examining Interventions for Balance

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<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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<tbody>
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<td><strong>Balance Training</strong></td>
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<tr>
<td><strong>Howe et al. (2005)</strong></td>
<td>UK</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>Acute</td>
<td>N=35</td>
<td>35 acute stroke patients were randomly assigned to receive usual care + an additional 12 therapy sessions for 4 weeks aiming to establish better lateral weight transference in sitting or usual care. Main Outcome measures included: Lateral reach test, static standing balance, sit-to-stand-to-sit.</td>
<td>There were no significant differences between groups. However within groups over time, sway during static standing and time taken during dynamic reaching to return to initial position improved.</td>
</tr>
<tr>
<td><strong>Marigold et al. (2005)</strong></td>
<td>Canada</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>&gt;1yr</td>
<td>N=61</td>
<td>61 community-dwelling chronic stroke patients were randomized to an exercise program that emphasized both stretching and weight-shifting or agility. Sessions were one hour in length, 3 x per week and continued for 10 weeks. Falls were tracked for 1 year from the start of the interventions.</td>
<td>There was no significant difference between the groups in the number of falls. There were 75 falls in the stretching group (16 people) and 25 falls in the agility group (11 people)(p=0.20).</td>
</tr>
<tr>
<td><strong>Allison et al. (2007)</strong></td>
<td>UK</td>
<td>RCT</td>
<td></td>
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<td></td>
<td>17 stroke rehabilitation patients were randomized to receive conventional physiotherapy for the duration of their</td>
<td>At the end of 12 weeks the only significant difference between groups was in the change in Berg Balance scores from baseline, favouring the</td>
</tr>
</tbody>
</table>
Mobility and the Lower Extremity

Krawczyk et al. (2014)
Poland
RCT
PEDro=3
Mean=39.6
NStart=51
NEnd=51

Population: Mean age=59.0±10.0yr; Gender: Males=38, Females=13.
Intervention: Participants were randomly allocated either to the standard rehabilitation group, or to the “closed chain” group where the exercises engage the entire involved side of the body during rehabilitation while maintaining vertical trunk orientation. Assessments were conducted prior to the rehabilitation program, after 6 weeks of the program, and after another 6 weeks of physiotherapy (at the end of the rehabilitation program).
Outcomes: Gait; stance phase; single stance phase (%), pelvic tilt; range of pelvic tilt; step width; hip and knee range in sagittal plane; speed; cadence; step length; Fugl Meyer Assessment (FMA); Berg Balance Scale (BBS).

1. No significant differences between the standard rehabilitation group and the closed-chain group was found at any time point for any of the outcome measures.

Mun et al. (2014)
Korea
RCT
PEDro=3
Mean>6mo
NStart=30
NEnd=19

Population: Unstable support surface group (USS; N=15): Mean age=56.6±13.9yr; Gender: unspecified. Stable support surface group (SSS; N=15): Mean age=66.3±10.2yr; Gender: unspecified.
Intervention: Participants were randomly allocated either to the unstable support surface (USS) group, or to the stable support surface (SSS) group. The intervention consisted of 15 minutes of support surface training plus 15 minutes of gait training.
Outcomes: Gait; Berg Balance Scale (BBS); Timed Up and Go (TUG); 10-meter Walk Test (10MWT); 6-min Walk Test (6MWT); step length (affected, unaffected).

1. A significant improvement in the USS group was found regarding the BBS, TUG, 6MWT, and the step-length for both the affected and unaffected sides (all p<0.05).
2. The SSS group improved significantly on the TUG, and on the 6MWT (both p<0.05).

Puckree et al. (2014)
South Africa
RCT
PEDro=6
TPS=NA
NStart=50
NEnd=50

Population: Experimental Group (EG; N=25): Age group: (0-34)=0; (35-39)=2; (50-74)=22; (>75)=1; Gender: Males=11, Females=14. Control Group (CG; N=25): Age group (0-34)=1; (35-39)=6; (50-74)=16; (>75)=2; Gender: Males=15, Females=10.
Intervention: The EG received a program of physiotherapy that was focused on balance

1. The EG showed an improvement in post-test scores, which was statistically significant (p<0.01). The strength of this association was strong (R²), and the effect size was medium (ES=0.532).
2. There were no statistically significant differences between groups for BBS.
and stability exercises. The CG received regular physiotherapy.

**Outcomes:** Balance: Berg Balance Scale (BBS).

<table>
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<tr>
<th><strong>Tang et al. (2014)</strong></th>
<th>China</th>
<th>RCT</th>
<th>PEDro=9</th>
<th>TPS$_{CBA}$=16.8±4.9d</th>
<th>TPS$_{ECBA}$=16.6±5.05d</th>
<th>N$_{Start}$=48</th>
<th>N$_{End}$=48</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> CBA (N=24): Mean age=66.9±4.1yr; Gender: Males=17, Females=7. ECBA (N=24): Mean age=68.2±4.1yr; Gender: Males=16, Females=8.</td>
<td><strong>Interventions:</strong> The two intervention groups in this study were the Contemporary Bobath Approach (CBA)-only group; and the Early sitting, standing, and walking (in conjunction with the CBA (ECBA) or ECBA-combined group; Balance: Berg Balance Score (BBS).</td>
<td><strong>Outcomes:</strong> Berg Balance Scale (BBS); STREAM; Demographic Recording Form.</td>
<td><strong>1.</strong> Lower extremity mobility $[F(1, 46)=20.2, \eta^2=0.305, P&lt; .001]$, and basic mobility $[F(1, 46)=20.6, \eta^2=0.310, P&lt; .001]$ and overall STREAM $[F(1, 46)=11.7, \eta^2 = 0.203, P &lt; .01]$ scores were higher in the ECBA group than the CBA group; these findings were statistically significant; and basic mobility, , domains and the overall STREAM scores.</td>
<td><strong>2.</strong> After treatment, the ECBA group had higher BBS scores than the CBA group at 4 weeks $F(1,46)=35.4, \eta^2=0.435, p&lt;0.001$, and 8 weeks, $F(1, 54)=73.1, \eta^2=0.614, p&lt;0.001$.</td>
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</table>

**Trunk Training**

<table>
<thead>
<tr>
<th><strong>Verheyden et al. (2009)</strong></th>
<th>Belgium</th>
<th>RCT</th>
<th>PEDro=6</th>
<th>TPS=NA</th>
<th>N=33</th>
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<td>33 patients admitted for inpatient rehabilitation were randomly assigned to an experimental group (n = 17) or a control group (n = 16). In addition to conventional therapy, the experimental group received 10 hours of individual and supervised trunk exercises; 30 minutes, 4 times a week, for 5 weeks. Trunk performance was evaluated by the Trunk Impairment Scale (TIS) and its subscales of static and dynamic sitting balance and coordination, before and after treatment.</td>
<td></td>
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<td>No significant pretreatment differences were found between the 2 groups. Following treatment, there were significant improvements in the mean TIS scores of patients in both groups. A significantly greater improvement was noted in the experimental group compared to the control group for the dynamic sitting balance subscale only.</td>
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<table>
<thead>
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<th><strong>Karthikbabu et al. (2011)</strong></th>
<th>India</th>
<th>RCT</th>
<th>PEDro=8</th>
<th>TPS$_{Mean}$=12dy</th>
<th>N=30</th>
</tr>
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<tbody>
<tr>
<td>30 inpatients, an average of 12 days following stroke who were able to sit for 30 seconds were randomized to one of two study groups. Patients in the experimental group performed task-specific trunk exercises on an unstable surface (physio ball) while the control group performed them on a stable surface (plinth). In addition to regular acute physiotherapy, both the groups underwent 1 hour of trunk exercises a day, four days a week for three weeks. The main outcome measures were the Trunk Impairment Scale and the Brunel Balance Assessment, assessed before and after treatment.</td>
<td></td>
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<td>Patients in both groups had improved over the study period. Patients in the experimental group improved significantly more than those in the control group. Mean change scores for the total Trunk Impairment Scale scores were 7.93 vs. 4.87, $p&lt;0.0001$ Mean change scores for the Brunel Balance Assessment were significantly greater for patients in the experimental group (6.2 vs. 4.4, $p&lt;0.0001$).</td>
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<table>
<thead>
<tr>
<th><strong>Lim et al. (2012)</strong></th>
<th>Korea</th>
<th>RCT</th>
<th>PEDro=4</th>
<th>TPS=Chronic</th>
<th>N=21</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 patients with hemiplegia after stroke were randomized to either the intervention (n=10) or control group (n=11). The intervention involved 8 weeks (4 sessions per week for 30-35 min each) of an abdominal drawing in maneuver using a pressure biofeedback unit, followed by a bridge exercise. The control group only had to perform the bridge exercise. Outcomes were assessed at baseline, 4 weeks and 8 weeks and involved an assessment of sway area, sway length and sway velocity.</td>
<td></td>
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<td></td>
<td>The intervention group experienced statistically significant improvements in sway area, path length and velocity over time ($p&lt;0.05$). There were no significant changes in scores among the control group. Compared to the control group, the intervention group had significantly better scores at 8 weeks ($p&lt;0.05$).</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro Score</td>
<td>TPS Group</td>
<td>N at Start</td>
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<tr>
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<tr>
<td>Bülükavcı et al. (2016)</td>
<td>Turkey</td>
<td>RCT</td>
<td>5</td>
<td>EG=33.4±11.4d</td>
<td>65</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CG=38.5±19.9d</td>
<td></td>
</tr>
<tr>
<td>Chung et al. (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>EG=12.88±7.16mo</td>
<td>16</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>CG=9.63±4.86mo</td>
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<tr>
<td>Jung et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>7</td>
<td>EG=15.3±9.5mo</td>
<td>18</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>CG=14.4±11.2mo</td>
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<tr>
<td>Saeyes et al. (2012)</td>
<td>Belgium</td>
<td>RCT</td>
<td>7</td>
<td>EG=35d</td>
<td>33</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>CG=</td>
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</table>

33 patients, an average of 35 days following stroke were randomly assigned to an experimental group (n = 18) or a control group (n = 15). In addition to conventional therapy, patients in the experimental group received 16 hours of truncal exercises. The control group received 16 hours of sham treatment. Outcomes were assessed at baseline and at the end of treatment and included the Trunk Impairment Scale (TIS) and the Tinetti Test. The Romberg with eyes open and eyes closed, Four Test Balance Scale (FTBS), Berg Balance Scale (BBS).

Patients in the experimental group performed significantly better on all on the outcomes: TIS (P < .001), Tinetti Test (P < .001), FTBS (P = .014) and BBS (P = .007).

**Population:**

**EG:** N=8; Mean age=44.37±9.90yr; Gender: Males=5, Females=3. **Control Group (CG):** N=8; Mean age=48.38±9.72yr; Gender: Males=7, Females=1.

**Intervention:** The EG received core stabilization exercises that were performed three subparts, bed exercises, wedge exercises, ball exercises using a Swiss ball; this was in addition to a general training program: 5 sessions, 60min/wk, for 4weeks. The control group only received a general training program.

**Outcome:** Timed Up-and-Go test (TUG); step length; stride length; gait velocity.

1. The EG demonstrated statistically significant differences in TUG test scores; this was marked by reductions in the TUG test from 33.06±18.39 sec to 27.64±13.73 sec (p=0.029). However, the CG did not demonstrate statistically significant differences in TUG test scores before-and-after the intervention period.
2. There were no statistically significant differences between groups observed in affected side step length or stride length.
3. The only statistically significant difference observed between the core group and CG was in gait velocity (p=0.039).

**Population:** Weight-shift training group (WST; N=9): Mean age=51.9±10.3yr; Gender: Males=7, Females=2. **Control Group (CG; N=8):** Mean age=57.91±8.5yr. Gender: Males=6, Females=2.

**Intervention:** The EG was the WST group, and they received a weight-shift training program for 30 mins. The CG received a conventional exercise program for 60 mins, 5 times per week for 4 weeks for both groups.

**Outcomes:** Timed Up-and-Go test (TUG).

1. There were statistically significant reductions in the TUG test scores indicating an improvement. The results showed that this improvement was greater in the WST group than the CG (p<0.05).
2. The results of this study suggest that weight-shifting is beneficial for improving trunk control and proprioception in patients with chronic hemiparetic stroke.

**Population:** Experimental Group (EG; N=33): Mean age=62.6±10.5yr; Gender: Males=17, Females=16. **Control Group (CG; N=32):** Mean age=63.6±10.4yr; Gender: Males=15, Females=17.

**Intervention:** The EG preformed trunk exercises, along with the conventional exercise program that the CG received. Training was 2h/d 3x/wk for 3wk for both groups. Outcomes were assessed at baseline and 3mo after treatment.

**Outcomes:** Brunnstrom Scale (BS); Berg Balance Scale (BBS); Trunk Impairment Scale.

1. There were significant improvements in the EG compared to the CG on the BS lower extremity score, BBS, FIM, and RMI (p=0.001 for all).
2. There were no significant differences observed on the BS upper extremity score or hand score.
3. There were no significant differences between the EG and CG on the TIS.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS EG</th>
<th>TPS CG</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Summary</th>
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<tbody>
<tr>
<td>Fujino et al. (2016)</td>
<td>Japan</td>
<td>RCT</td>
<td>6</td>
<td>10.6±2.7d</td>
<td>10.2±2.6d</td>
<td>43</td>
<td>30</td>
<td>Experimental Group (EG, N=15): Mean age=67.9±7.8yr; Gender: Males=10, Females=5. Control Group (CG; N=15): Mean age=64.4±7.5yr; Gender: Males=11, Females=4.</td>
<td>The EG sat without leg support on a platform tilted 10° to the paretic side while the CG sat on a horizontal platform. Both groups were asked to move their trunk laterally from the paretic side to the non-paretic side. This was performed 60x/session, with 6 sessions/wk. Outcomes were assessed at baseline and post-intervention.</td>
<td>Stroke Impairment Assessment Set (SIAS); Trunk Control Test (TCT).</td>
<td>1. There was a significant group by time interaction on the TCT (p&lt;0.01), but not on the SIAS. 2. There was a significant time interaction on the SIAS and TCT (p&lt;0.01 for both).</td>
</tr>
<tr>
<td>Tung et al. (2010)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>6</td>
<td>26.9±16mo</td>
<td>12.8±12.3mo</td>
<td>32</td>
<td>32</td>
<td>32 chronic stroke subjects were randomized to receive one of 2 interventions. Subjects in both groups received 30 minutes of general physical therapy three times a week for four weeks. Subjects in the experimental group received additional sit-to-stand training for 15 minutes each time. The total amount of therapy received was 45 minutes in the experimental group and 30 minutes in the control group each time. Outcome measures assessed before and after treatment, included weight-bearing distribution during quiet standing, the directional control and maximal excursion during limits of stability test, the scores of Berg Balance Scale and the extensor muscle strength of lower extremity.</td>
<td></td>
<td>Stroke Impairment Assessment Set (SIAS); Trunk Control Test (TCT).</td>
<td>1. There was significantly greater improvement in the experimental group in directional control anteriorly (47.4 % to 62.6% vs. 68.7 % to 62.8 %, p = 0.028) and in affected hip extensor strength (19.3 % to 22.6% vs. 24.4% to 22.8 %, p = 0.006) compared with the control group. There were no other statistically significant differences between groups.</td>
</tr>
<tr>
<td>Fargalit et al. (2013)</td>
<td>Malaysia</td>
<td>RCT</td>
<td>8</td>
<td>1-7yr</td>
<td>1-7yr</td>
<td>40</td>
<td>40</td>
<td>Experimental Group 1 (EG1, N=20): Age range=40-80yr; Gender: Males=14, Females=6. Experimental Group 2 (EG2, N=20): Age range=40-80yr; Gender: Males=15, Females=5.</td>
<td>EG1 underwent sit-to-stand (STS) training with an asymmetrical foot position (affected foot placed behind unaffected foot) while EG2 trained with a symmetrical foot position (affected foot alongside unaffected foot). Patients completed 100 repetitions and a supervised exercise program 5/wk for 4wks. Assessments were conducted at baseline and at post-treatment.</td>
<td>Number of STS repetitions in 3mins; Berg Balance Scale (BBS); and Timed Up-and-Go Test (TUG).</td>
<td>1. Both groups demonstrated significant improvement in the number of STS repetitions from baseline to post-treatment (p&lt;0.001) but EG1 demonstrated significantly greater improvements when compared to EG2 (p&lt;0.001). 2. Both groups demonstrated significant improvement on the TUG from baseline to post-treatment (p&lt;0.001) but EG1 improved significantly more when compared to EG2 (p&lt;0.001). 3. Both groups demonstrated significant improvement on the TUG from baseline to post-treatment (p&lt;0.001) but EG1 improved significantly more when compared to EG2 (p=0.037).</td>
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<td>Kim et al. (2015)</td>
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### Mobility and the Lower Extremity

**Korea**  
**PCT**  
No Score  
TPS<sub>EG</sub>=26.6±14.61mo  
TPS<sub>CG</sub>=33.36±21.09mo  
N<sub>Start</sub>=23  
N<sub>End</sub>=23

Mean age=57.47±9.47yr; Gender: unspecified.  
Control Group (CG; N=11): Mean age=61.29±10.76yr; Gender: unspecified.  
**Intervention:** Participants preformed several tasks involving different conditions while doing sit-to-stand.  
G1 was not given instructions on foot placement, and G2 had their non-paretic foot constrained by supporting it on a step and the paretic foot was kept at ground level.  
Training was performed 5x/wk for 6wk.  
Outcomes were conducted at baseline and post-intervention.  
**Outcomes:** Biodex Balance System; Fall risk index; Timed Up and Go Test (TUG); Five Times Sit-To-Stand (5XSST); centre of pressure (COP); foot pressure (forefoot peak pressure; hind foot peak pressure; forefoot contact area; hind foot contact area).

**Liu et al.** (2016)  
China  
RCT  
PEDro=7  
TPS<sub>EG</sub>=3.7±1.1mo  
TPS<sub>CG</sub>=4.1±1.4mo  
N<sub>Start</sub>=50  
N<sub>End</sub>=50

**Population:** Experimental Group (EG, N=25): Mean age=48.9±10.5yr; Gender: Males=18, Females=7.  
Control Group (CG; N=25): Mean age=51.7±12.4yr; Gender: Males=16, Females=9.  
**Intervention:** The CG received sit-to-stand training with symmetrical foot position, while the participants in the EG were given modified sit-to-stand with the paretic foot placed posterior. This training was performed for 30min, 5x/wk for 4wk.  
Outcomes were assessed at baseline and post-intervention.  
**Outcomes:** Sit-to-Stand (STS: rise time; weight bearing (WB) of unaffected foot; WB affected foot; WB asymmetry); Standing balance (static balance; dynamic balance); Berg Balance Scale (BBS).

**Shumway-Cook et al.** (1988)  
USA  
RCT  
PEDro=4  
TPS<sub>Mean</sub>=37±15d  
N=50

Static force plate system was used to examine postural sway characteristics in 16 hemiplegic patients and 34 normal elderly subjects. Mean number of days since the time of stroke onset for patients was 37 ± 15 days. Effectiveness of postural sway biofeedback was compared to conventional physical therapy practices in establishing stance stability.

**Sackley & Lincoln** (1997)  
UK  
RCT  
PEDro=6  
TPS<sub>Range</sub>=4-63wk  
N=26

26 patients (time since stroke onset ranged from 4-63 weeks) were randomized to a visual feedback treatment group, which provided continuous data on weight distribution and weight shift activity during a sit to stand exercise or to a control condition. Both treatments were provided in 12 treatment sessions, over 4 weeks. Evaluations included

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**Force Platform Biofeedback**

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shumway-Cook et al.</strong> (1988)</td>
<td>USA</td>
<td>RCT</td>
<td>4</td>
<td>37±15d</td>
<td>50</td>
<td>Postural sway abnormalities in hemiplegic patients included significant mean lateral displacement of sway toward the non-affected leg and increased total sway area. Postural sway biofeedback was more effective than conventional loading of the affected leg. However, post-treatment changes in total sway area were not significantly different between the groups.</td>
</tr>
<tr>
<td><strong>Liu et al.</strong> (2016)</td>
<td>China</td>
<td>RCT</td>
<td>7</td>
<td>3.7±1.1mo</td>
<td>50</td>
<td>There were significant improvements in the EG rise time (p=0.024), WB unaffected foot (p=0.000), WB affected foot (p=0.000), WB asymmetry (p=0.000), static balance (p=0.032), dynamic balance (p=0.022), BBS (p=0.003).</td>
</tr>
</tbody>
</table>

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9. Mobility and the Lower Extremity  
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<table>
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<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Treatment Details</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wong et al. (1997)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>5</td>
<td>NA</td>
<td>60</td>
<td>60 stroke patients were randomized to receive one of two training methods: (1) Standing training table (STT): height-adjustable worktable, a pelvic belt and a suspension system to help the client maintain symmetry in an upright stance, while performing a task of pushing and pulling a load by means of resistive movements of the upper limb. The subject/therapist did not know how much weight is actually transferred to the affected leg during the training program; (2) Standing biofeedback training device (SBT): modification of STT with a real-time visual weight bearing biofeedback displays with numerical light-emitting diodes and balance scale and auditory alarm system. Patients were trained for 5 days a week for 3 to 4 weeks.</td>
<td>Ability to maintain stance by percentage of postural symmetry in the group trained with SBT was significantly better than that trained with STT at week 4. Immediate learning effect after the first day of training in group SBT was significantly better than group STT.</td>
</tr>
<tr>
<td>Walker et al. (2000)</td>
<td>Canada</td>
<td>RCT</td>
<td>4</td>
<td>&lt;80d</td>
<td>54-46</td>
<td>54 patients were randomized to 1 of 3 groups: (1) visual feedback training; (2) conventional balance training; and (3) control group. The 2 treatment groups received additional balance training given 5 days/wk for 3-8 wks, depending on length of rehabilitation stay. Patients were admitted within 4 months of stroke onset.</td>
<td>At 1-month follow-up there were no significant differences between the groups on any of the outcome measures over time.</td>
</tr>
<tr>
<td>Cheng et al. (2001)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>5</td>
<td>2.9mo</td>
<td>54</td>
<td>54 patients with hemiplegic stroke were randomly assigned to receive conventional stroke rehabilitation or conventional stroke rehabilitation plus symmetrical standing training and repetitive sit-to-stand training with a standing biofeedback trainer. Outcomes measures include: Occurrence of falls, sit-to-stand performance, including body-weight distribution, rate of rise in force, and sway in center of pressure (COP)</td>
<td>Patients receiving extra training demonstrated a significant improvement in sit-to-stand performance. Body weight was distributed more symmetrically in both legs with less mediolateral sway when rising and sitting down.</td>
</tr>
<tr>
<td>Geiger et al. (2001)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>15-538d</td>
<td>13</td>
<td>13 patients were randomized to receive either biofeedback training or regular balance training therapy. Both groups received interventions to improve balance and mobility 2-3 x/wk for 50 min for 4 wks while the experimental group received an additional 15 minutes of biofeedback training. Patients were able to stand without manual assistance for 2 minutes.</td>
<td>At 4 weeks, there were no significant differences observed between the 2 groups on either outcome measures.</td>
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<tr>
<td>Chen et al. (2002)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>4</td>
<td></td>
<td>41</td>
<td>41 hemiplegic, ambulatory stroke patients were randomly allocated to either a trained group or to a control group. The trained group received visual feedback balance training with</td>
<td>The trained group were able to use more ankle strategies than the control group but there was no significant difference in maximum stability and centre of gravity alignment between the groups in 2002.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>Duration</td>
<td>Sample Size</td>
<td>Population Details</td>
<td>Intervention Details</td>
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<tr>
<td>Yavuzer et al. (2006)</td>
<td>Netherlands</td>
<td>RCT</td>
<td>6</td>
<td>6mo</td>
<td>50</td>
<td>Rehabilitation inpatients, post stroke onset of 6 months were randomized to receive conventional rehab with (n=25) and without (n=25) additional balance training. Patients in the balance training group received 15 min of balance training once a day, 5 days a week for 3 weeks, using the Nor-Am Target Balance Training System. Time-distance and kinematic gait parameters were assessed following treatment.</td>
<td>Pelvic excursion in frontal plane improved significantly more in the experimental group compared with control (p=0.021). The difference between before-after change scores of the groups was significant for pelvic excursion in frontal plane (p=0.039) and vertical ground reaction force (p=0.030) in favour of experimental group. The control group did not show any statistically significant difference regarding gait characteristics.</td>
</tr>
<tr>
<td>Eser et al. (2008)</td>
<td>Turkey</td>
<td>RCT</td>
<td>5</td>
<td>6mo</td>
<td>41</td>
<td>Rehabilitation inpatients with a median time since stroke of 6 months were randomly assigned to receive conventional stroke inpatient rehabilitation (n=19) or to receive 15 sessions of balance training (using force platform biofeedback) in addition to the conventional program(n=22). The main outcome measures assessed before and one-week after treatment included Brunnstrom staging, Rivermead Mobility Index, (RMI) and FIM.</td>
<td>Motor recovery, mobility and activity level improved significantly in both groups over the treatment period. Between-group difference of mean change score was not significant for the Brunnstrom stages, (0.23 vs. 0.26) RMI (2.9 vs. 2.2) or FIM score (10.7 vs. 11.5).</td>
</tr>
<tr>
<td>Rao et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>NA</td>
<td>28</td>
<td>Population: Experimental group (EG; N=14): Mean age=57.86±15.51yr; Gender: Males=11, Females=3. Control Group (CG; N=14): Mean age=60.57±9.60yr; Gender: Males=12, Females=2. Intervention: The EG received 1 week of treatment on the basis of retraining balance utilizing visual biofeedback while provided with a body weight support harness system. The CG received conventional therapy; this group was offered three sessions of balance training while standing on the floor, and learning toward the targets represented by therapists’ hands. Outcomes: Fugl-Meyer Balance (FM-B); Functional Independence Measure for gait (FIM-G); Fugl-Meyer lower extremity assessment (FM-LE).</td>
<td>1. The results showed that both groups improved with respect to FM-B scores and (p&lt;0.001); this was indicative of statistically significant within-group differences. There were no statistically significant between-group differences for this outcome. 2. Both groups demonstrated improvements in FIMG scores and findings from ANOVA showed that the effect of treatment for both groups was statistically significant (p&lt;0.001). There were no statistically significant between-group differences for this outcome.</td>
</tr>
<tr>
<td>Yoon et al. (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>2</td>
<td>3mo</td>
<td>24</td>
<td>24 patients at least 3 months post-cerebrovascular event who experienced hemiplegia were randomized to one of three groups for assessment of a balance training system intervention. The groups included self-controlled feedback (n=8), yoked feedback (n=8) or no feedback (control, n=8).</td>
<td>1. During the acquisition phase, the body sway amplitudes were significantly lower in the self-controlled and yoked feedback groups compared to controls (p&lt;0.05). During the retention phase, body sway amplitudes were significantly lower in the self-controlled feedback group compared to the yoked group.</td>
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were asked to stand on the footplates of the balance system and their left/right and anterior/posterior sway were assessed over a series of 4 blocks (each block consisting of 10 trials for 10 seconds each). The protocol involved two phases – an acquisition phase (including the corresponding feedback) and a retention phase (with no feedback).

**Population:** Experimental Group (EG; N=26): Mean age=48.1±4.4yr; Gender: Males=20, Females=6. Control Group (CG; N=26): Mean age=45.3±4.2yr; Gender: Males=16, Females=10.

**Intervention:** The EG received 30-minute sessions of Space Balance 3D training and conventional rehab exercise for a total of 15 sessions. The intervention ran for a 3-week period. The CG performed conventional rehabilitation exercise only.

**Outcomes:** Berg Balance Scale (BBS); Timed Up and Go (TUG) test; Postural Assessment Scale (PASS).

1. The results revealed a nonsignificant interaction effect between group and time period for both groups before and after interventions in the BBS score, TUG score, and PASS score.
2. There were no statistically significant differences between the EG and the CG for BBS, TUG, and PASS scores.
3. There were statistically significant within-group differences for each of BBS, TUG and PASS scores, as indicated by an improvement in these scores. (p<0.05).

### Virtual Reality

**Kim et al.** (2009)  
South Korea  
RCT  
PEDro=6  
TPS>1yr  
N=24

- 24 chronic, hemiparetic stroke patients were randomly assigned to either an experimental group (n = 12) or a control group. Both groups underwent conventional physical therapy, 40 mins a day, 4 days a week for 4 wks. The experimental group received an additional 30 mins of virtual reality therapy each session. Balance performance was determined by the Balance Performance Monitor and Berg Balance Scale tests. Gait performance was determined by the 10-m walking test and Modified Motor Assessment Scale.

1. Following treatment there was significantly greater improvement among subjects in the experimental group on the following outcome measures: Berg Balance Scale scores, balance and dynamic balance angles (ability to control weight shifting), velocity, Modified Motor Assessment Scale scores, cadence, step time, step length, and stride length.

**Jung et al.** (2011)  
Republic of Korea  
RCT  
PEDro=4  
TPS>3mo  
N=22

- 22 patients, at least 3 months post stroke were randomized to either (a) 3D exercise group (3DG): (n=11) which received 3D exercise using the 3D Thera-balance system (20 mins/session) (b) Weight shifting exercise group (WSG): (n=11) which received weight shifting exercise (20 mins/ session). In addition, both groups received neurophysiological treatment for 30 mins/session. Interventions were carried out 5/week for 6 weeks. Outcomes were assessed using the Berg Balance Scale (BBS) and the 10-meter timed walk (10MWT) post intervention.

1. Both groups showed significant improvements in balance and walking ability from baseline.
2. After 6 weeks of intervention there was a significant difference between groups in terms of the BBS scores (3DG: 48.6±5.6, WSG: 37.9±5.1; p<0.05). There was no significant difference between groups on the 10MWT post intervention (p>0.05).

**Cho et al.** (2012)  
Korea  
RCT  
PEDro=5  
TPS>6mo  
N=22

- 22 patients with hemiparesis were randomly allocated to either intervention (n=11) or control (n=11) groups. The intervention group received virtual reality balance training for 6 weeks (20 minutes/session, 3 times/week) in

1. The intervention and the control group both experienced statistically significant improvements in dynamic balance scores as measured by the BBS and the TUG (p<0.05 for the control group TUG score, p<0.001 for all
addition to standard rehabilitation therapy. The control group received standard therapy. Static and dynamic balance were assessed pre and post intervention (baseline and 6 weeks). Static balance was assessed using postural sway velocity (anterior/posterior and medio-lateral movement). Dynamic balance was assessed using the BBS and TUG. Significantly greater improvements were experienced by patients in the intervention group compared to the control group on the BBS and TUG (p<0.05, p<0.001 respectively). There were no differences between the groups for static balance measures.

Kim et al. (2012)  
Korea  
RCT  
PEDro=4  
TPS<sub>EG</sub>=12.6±7.12mo  
TPS<sub>CG</sub>=12.85±6.06mo  
N=22  

20 patients with functional impairment after stroke were randomized either to the intervention or control group. Complete data was available for 17 patients, 7 in the control group and 10 in the intervention group. Both groups received 30 minutes of exercise and 15 minutes of electrical stimulation prior to the intervention. The intervention involved 9 sessions (30 minute sessions, 3x per week for 3 weeks) of Nintendo Wii (tennis and boxing games). Outcomes were assessed before the intervention and at 3 weeks (after completion of the intervention), and included the postural assessment scale (PASS), the modified motor assessment scale (MMAS) and the functional independence measure (FIM).

Barcala et al. (2013)  
Brazil  
RCT  
PEDro=7  
TPS<sub>EG</sub>=12.3±7.1mo  
TPS<sub>CG</sub>=15.2±6.6mo  
N<sub>Start</sub>=20  
N<sub>End</sub>=20  

Population: Experimental (EG; N=10): Mean age=65.2±12.5yr; Gender: Males=5, Females=5. Control Group (CG; N=10): Mean age=63.5±14.5yr; Gender: Males=4, Females=6.  
Intervention: The EG received Balance training with visual biofeedback using Wii Fit together with conventional physical therapy. The CG received conventional physical therapy (COP) alone. Outcomes were assessed before and after the intervention.  
Outcomes: Stabilometry, Berg Balance Scale (BBS); Timed Up-and-Go test (TUG); Functional Independence Measure (FIM).  

1. Results showed that there was a greater control of static and dynamic balance, lesser time needed for the execution of orthostatic mobility and improved performance in the executive of functional activities in both experimental and CGs, during the post-intervention period. There were no statistically significant differences between the experimental and CGs with respect to these outcomes.  
2. Intragroup analyses showed that both groups demonstrated statistically significant improvements for all of these outcomes.

Rajaratnam et al. (2013)  
Singapore  
RCT  
PEDro=4  
TPS<sub>EG</sub>=14.7±7.5mo  
TPS<sub>CG</sub>=15.2±6.3mo  
N<sub>Start</sub>=19  
N<sub>End</sub>=19  

Intervention: The EG received 40 minutes of conventional therapy and 20 minutes of balance trunk control training using VR Microsoft Kinect or Nintendo Wii-Fit. The CG received 60 minutes of conventional therapy only.  
Outcomes: Berg Balance Scale; The Timed Up-and-Go test, Centre of Pressure using Nintendo Wii-Fit.

1. In all outcome measures after intervention, there were no statistically significant differences between the experimental and CGs.  
2. In the EG, there was a statistically significant improvement in TUG scores after intervention.  
3. In the CG, there was a statistically significant improvement in TUG scores after conventional therapy.
Singh et al. (2013)  
Malaysia  
PCT  
No Score  
TPS<sub>EG</sub>=40.5mo  
TPS<sub>CG</sub>=34.9mo  
N<sub>Start</sub>=36  
N<sub>End</sub>=28

**Population:** Experimental Group (EG; N=15): Mean age=65.4±9.8yr; Gender: unspecified.  
Control Group (CG; N=13): Mean age=40.5±11.8yr; Gender: unspecified.  
**Intervention:** Participants were allocated either to the EG and received 30 minutes of virtual reality (VR) balance games in addition to 90 minutes of standard group exercise therapy, or to the CG and received only routine standard group exercise therapy for 2 hours. Both groups received 12 therapy sessions, each session lasting 2 hours, given twice per week, for 6 continuous weeks. Participants were assessed before the intervention and immediately completion of the six weeks of intervention.  
**Outcomes:** Timed Up-and-Go test (TUG); Thirty-second sit to stand test (30sSTS); timed ten-meter walk test (T10mWT); six-minute walk test (6MWT); overall balance score (OBS); Barthel Index (BI).

1. Both groups demonstrated a significant improvement from pre- to post-training on the TUG (p=0.02), and on the 30sSTS (p=0.001).  
2. No significant improvements were found on the remaining outcome measures within either group.*  
3. No significant differences were found between the two groups on any of the outcome measures.*

Bower et al. (2014)  
Australia  
RCT  
PEDro=8  
TPS=NA  
TPS<sub>BG</sub>= 25.4±16.4d  
TPS<sub>ULG</sub>=24.2±20.8d  
N<sub>Start</sub>=30  
N<sub>End</sub>=21

**Population:** Balance Group (BG; N=17): Mean age=61.9±13.6yr; Gender: Males=8, Females=9. Upper Limb Group (ULG; N=13): Mean age=65.9±16.2yr; Gender: Males=9, Females=4.  
**Intervention:** Participants in the Upper Limb Group used the ‘Wii Sports’ and/or ‘Wii Sports Resort’ packages in a seated position. Participants in the Balance Group undertook standing balance activities using the ‘Wii Fit Plus’ package. These participants were involved in tasks that included static poses. Both groups participated three 45-minute sessions per week over two to four weeks in addition to standard care.  
**Outcomes:** Feasibility; Adherence; Acceptability; Safety outcomes; Functional Reach Test (FRT); Timed Up and Go (TUG); Balance; Short Falls Efficacy Scale – International (SFES-I); Upper Limb – Motor Assessment Scale (MAS-UL); STREAM.

1. There were statistically significant improvements observed among patients in both groups for the primary outcome measures (Step Test and Functional Reach Test).  
2. There were no statistically significant differences between groups regarding the Functional Reach outcome.  
3. A non-significant but moderate-to-high (d=0.75) effect size was found for the Balance Group on the Functional Reach test, at the 2-week assessment point.  
4. There were improvements observed for the majority of secondary outcomes over time in both groups.  
5. The Balance Group participants demonstrated great improvements in Wii Balance Board-derived measures with small to large effect sizes (d=0.30 to 1.00) at four weeks (p=0.0007 to0.048)  
6. At 2 and 4-week assessments larger, statistically non-significant improvements in the upper limb subscale of the STREAM and the Upper Limb – Motor Assessment Scale in the Upper Limb Group compared to the Balance Group.

Lee et al. (2014)  
Korea  
RCT  
PEDro=7

**Population:** Augmented Reality (AR; N=10): Mean age=47.9±12.0yr; Gender: Males=8, Females=2. Control Group (CG; N=11): Mean age=54.0±11.9yr; Gender: Males=6, Females=5.

1. Both groups improved significantly on the TUG step length for the paretic side, (and the stride length for both the paretic side, and the nonparetic side.)
Intervention: Participants were randomly allocated either to the CG or the EG. All participants received general physical therapy for 30 minutes per session, 5 days per week, for 4 weeks. The EG received an additional augmented reality (AR)-based postural control training for 20 minutes per day, 3 days per week, for 4 weeks.

Outcomes: Timed Up-and-Go Test (TUG); Berg Balance Scale (BBS); gait velocity; cadence; step length; stride length.

2. The AR showed significant improvements on the BBS (p=0.007), gait velocity (p=0.013), cadence (p=0.047), and step length for the nonparetic side (p=0.007).

3. A significant time x group interaction was found regarding the gait velocity (P=0.030), step length for the paretic and the nonparetic side (p=0.042, p=0.011), and the stride length for the paretic and the nonparetic side (p=0.029, p=0.018).


Intervention: Participants were randomly allocated to either the treatment group and performed virtual reality (VR) exercises in the form of games in a standing position, or to the CG and performed the VR games in a seated position. Each session lasted 20 minutes, and each group completed 10 to 12 sessions. Participants were assessed before VR training, immediately after the final training session (POST), and after 1 month post training completion (1 MO).

Outcomes: Timed Up-and-Go test (TUG); two-minute walk test (TMWT); Chedoke McMaster Stroke Assessment Scale Leg domain (CMSA-Leg).

1. Both the experimental and the CGs met the minimal clinical important difference values from baseline to post-intervention on the TMWT and on the TUG.

2. More individuals in the EG than in the CG showed improvements on the CMSA-leg at post (p=0.04) and at 1mo. (p=0.02).
walking for 10m was further reduced by 6% in both groups.
5. Findings also showed improvements in balance in the Wii group, independent of improvements for the 10 m walking test.
6. Overall, the results of the study show that a video game-based therapy performed using Wii Fit may be effective in enhancing balance and independency in activity of daily living in patients affected by subacute stroke.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Start</th>
<th>End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Llorens et al. (2015b)</td>
<td>Spain</td>
<td>RCT</td>
<td>8</td>
<td>NA</td>
<td>22</td>
<td>20</td>
<td>Experimental Group (EG; N=15): Mean age= 55.60±7.29yr; Gender: Males=10, Females=5. Control Group (CG; N=15): Mean age=55.47±9.63yr; Gender: Males=7, Females=8.</td>
<td>Twenty 45-min training sessions with the tele-rehabilitation system, conducted 3 times a week in the clinic or in the home. The CG received the intervention in-clinic while the EG received the intervention from home.</td>
<td>Berg Balance Scale (BBS); Performance-Oriented Mobility Assessment (balance (POMA-B) and gait (POMA-G) scales; Brunnel Balance Assessment (BBA); System Usability Scale (SUS); Intrisinc Motivation Inventory (IMI).</td>
</tr>
<tr>
<td>Yatar &amp; Yildirim (2015)</td>
<td>Turkey</td>
<td>RCT</td>
<td>4</td>
<td>≤3.70yr</td>
<td>33</td>
<td>30</td>
<td>Experimental Group (EG; N=15): Mean age=62.8yr; Gender: Males=6, Females=9. Control Group (CG; N=15): Mean age=56.6yr; Gender: Males=7, Females=8.</td>
<td>Patients were randomized to receive progressive balance training (CG) or balance training with Wii (EG). Training was provided 1hr/d, 3d/wk for 4wk.</td>
<td>Berg Balance Scale (BBS); Timed Up &amp; Go Test (TUGT); Functional Reach Test (FRT); Activities-Specific Balance Confidence Scale (ABCS); Dynamic Gait Index (DGI); Frenchay Activities Index (FAI).</td>
</tr>
<tr>
<td>Hung et al. (2016)</td>
<td>China</td>
<td>RCT</td>
<td>5</td>
<td>≤17.50mo</td>
<td>27</td>
<td>23</td>
<td>Experimental Group (EG; N=12): Median age=52.75yr; Gender: Males=8, Females=4. Control Group (CG; N=11): Median age=55.20yr; Gender: Males=8, Females=3.</td>
<td>All participants received conventional physiotherapy and occupational therapy 3d/wk for 6wk. The EG also received interactive videogame (Tetrax) biofeedback balance training 20min/d, 3d/wk for 6wk.</td>
<td>Timed Up and Go (TUG); Forward Reach Test (FRT).</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS EG</td>
<td>TPS CG</td>
<td>N Start</td>
<td>N End</td>
<td>Population</td>
<td>Intervention</td>
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<tr>
<td>In et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>12.54±4.14mo</td>
<td>13.58±5.28mo</td>
<td>30</td>
<td>25</td>
<td>Experimental Group (EG; N=13): Mean age=57.31±10.53yr; Gender: Males=8, Females=5. Control Group (CG; N=12): Mean age=54.42±11.44yr; Gender: Males=7, Females=5.</td>
<td>All participants received conventional rehabilitation for 30min. The EG also received lower limb virtual reality reflection therapy for 30min, 5x/wk for 4wk. Outcomes were assessed at baseline and post-intervention.</td>
</tr>
<tr>
<td>Şimşek &amp; Cekok (2016)</td>
<td>Turkey</td>
<td>RCT</td>
<td>7</td>
<td>50.6±15.04d</td>
<td>59.9±30.99d</td>
<td>44</td>
<td>42</td>
<td>Experimental Group (EG; N=20): Mean age=54.15±20.29yr; Gender: Males=15, Females=5. Control Group (CG; N=22): Mean age=61.5±11.63yr; Gender: Males=14, Females=8.</td>
<td>The EG received balance and upper limb training with a Nintendo Wii and the CG received Bobath neurodevelopmental treatment for the upper limb, balance, strength, and gait. Treatments were applied for 45-60min/d, 3/wk for 10wk. Outcomes were assessed at baseline and post-intervention.</td>
</tr>
<tr>
<td>Bayouk et al. (2006)</td>
<td>Canada</td>
<td>RCT</td>
<td>4</td>
<td>5.7±6.9</td>
<td>7.1±12.5</td>
<td>16</td>
<td>16</td>
<td>16 hemiparetic subjects &gt;6 months post stroke participated in an 8-week (1 hr 2x/week) task-oriented exercise program focusing on balance and mobility exercises and were randomized to one of two groups. Exercises were performed under normal conditions by the control group and under conditions of vision (eyes closed/open) and surface manipulation (firm/hard surface) by the experimental group. Pre- and post-test assessments involved the measurement of the center of pressure (COP) displacement during double-legged stance and sit-to-stand under four sensory conditions: (1) eyes open, normal surface; (2) eyes open, soft surface; (3) eyes closed, normal surface; and (4) eyes closed, soft surface, as well as the 10m walking test.</td>
<td>Results showed significant improvements (P&lt;0.05) in COP displacement under sensory conditions (1) and (2) for the experimental group only, and limited changes for the sit-to-stand in both groups after training. Significant improvements (P&lt;0.05) were also found in both groups for the walking test.</td>
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<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;</td>
<td>N&lt;sub&gt;End&lt;/sub&gt;</td>
<td>Participants and Intervention details</td>
<td>Results</td>
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<tr>
<td>Yelnik et al. (2008)</td>
<td>France</td>
<td>RCT</td>
<td>7</td>
<td>3-15mo</td>
<td>68</td>
<td>68</td>
<td>68 stroke patients able to walk without human assistance were entered from 3 to 15 months (mean, 7 months) after a first hemispheric stroke were randomized to a 4-week program of either multisensory rehabilitation, an approach based on higher intensity of balance tasks and exercise during visual deprivation, or to a conventional neurodevelopmental theory-based treatment (NDT) that used a general approach. The primary outcome was the 30 day Berg Balance Scale (BBS) score. Secondary outcomes included velocity, double stance phase, climbing 10 steps, amount of walking per day, FIM and the Nottingham Health Profile (NHP) assessment at 30 and 90 days.</td>
<td>All subjects improved significantly in balance and walking parameters. There was no significant between group differences on the primary outcome. There were significant differences in FIM scores and NHP scores at both 30 and 90 days, favouring the experimental group.</td>
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<tr>
<td>Varoqui et al. (2011)</td>
<td>France</td>
<td>RCT</td>
<td>6</td>
<td>&lt;6mo</td>
<td>24</td>
<td>24</td>
<td>24 hemiplegic patients within 6 months post stroke were randomized to one of 3 groups (i) naFB: coordination biofeedback originating from the unaffected side (ii) aFB: coordination biofeedback originating from the affected side (iii) control: performance of a stand-up task. The interventions were carried out with the help of a customized postural coordination biofeedback system, where participants were asked to copy postural patterns projected on a screen. The study lasted 4 weeks and included 3 sessions per week. Outcomes were assessed at sessions 1, 6, 7 and 12. Outcomes assessed included lower extremity motor weakness, using a 5-point scale, spasticity, using the modified Ashworth scale (MAS), balance, with the help of the Berg balance scale (BBS) and the Postural assessment scale for stroke (PASS), gait capacity, using the Functional ambulation categories (FAC) and autonomy, using the FIM.</td>
<td>An improvement in baseline was seen for all groups, in all clinical measures except the MAS (p&lt;0.01). A significant group x test interaction was reported for the FIM, where the naFB and aFB groups made significant gains (18.33 and 19 points) compared to the control group (8 points) (p&lt;0.05). Significant between group differences were not seen in terms of balance.</td>
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<tr>
<td>Hosseini et al. (2012)</td>
<td>Iran</td>
<td>RCT</td>
<td>6</td>
<td>&gt;6mo</td>
<td>30</td>
<td>30</td>
<td>30 persons with stroke were randomized into an experimental and control group. The experimental group received 15 min mental practice sessions and 30 mins of conventional therapy. The control group received 45 minutes of conventional therapy. The interventions were carried out 3days/week for 5 weeks. Timed up and go (TUG) and the Berg Balance Scale (BBS) were used to assess outcomes post intervention at 2 weeks follow up.</td>
<td>Although both groups improved significantly from baseline, there were significant differences between groups (p&lt;0.001) on the TUG and BBS post intervention.</td>
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<tr>
<td>Lee et al. (2013b)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td>&gt;6mo</td>
<td>40</td>
<td>40</td>
<td>Patients were randomized to receive conventional rehabilitation alone (control) or with visual feedback training (treatment). Rehabilitation was delivered 60min/d, 5d/wk for 4wk. Feedback was delivered 30min/d, Static and dynamic balance significantly improved only in the treatment group after training, and was significant when compared to the control group.</td>
<td>Static and dynamic balance significantly improved only in the treatment group after training, and was significant when compared to the control group.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Randomized Controlled Trial (RCT)</td>
<td>PEDro Score</td>
<td>TPS (m)</td>
<td>Start (N)</td>
<td>End (N)</td>
<td>Population Details</td>
<td>Intervention Details</td>
<td>Outcomes Details</td>
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<tr>
<td>Lee et al. (2015)</td>
<td>Republic of Korea</td>
<td>RCT</td>
<td>5</td>
<td>N=22</td>
<td>5d/wk for 4wk</td>
<td></td>
<td>EG: N=18; Age &lt;65=14, ≥65=4; Gender: Male=9, Female=9. CG: N=18; Age &lt;65=14, ≥65=4; Gender: Male=11, Female=7.</td>
<td>All patients received proprioception training for 5d/wk for 8wks. The EG received 25min of proprioception training and 5min motor imagery training per session while the CG received 30min of proprioception training.</td>
<td>Korean Berg Balance scale (K-BBS), Timed Up-and-Go test (TUG), inclinometer measurements.</td>
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<tr>
<td>Ghomashchi (2016)</td>
<td>Iran</td>
<td>RCT</td>
<td>3</td>
<td>N=31</td>
<td></td>
<td></td>
<td>EG: N=16; Mean age=64.73±7.4yr; Gender: unspecified. CG: N=15; Mean age=55.75±13.96yr; Gender: unspecified.</td>
<td>Both groups received conventional physical therapy and balance training exercises. The EG also received visual biofeedback during balance training and the CG did not. Training sessions were 1h, 3x/wk for 4wk. Outcomes were assessed at baseline, mid-point (after the 6th session), and post-intervention.</td>
<td>Centre of Pressure (COP: medial-lateral (ML); anterior-posterior (AP)).</td>
</tr>
<tr>
<td>Jang &amp; Lee (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>N=28</td>
<td></td>
<td></td>
<td>EG: N=13; Mean age=64.77±11.27yr; Gender: Male=6, Female=7. CG: N=15; Mean age=67.47±13.0yr; Gender: Male=8, Female=7.</td>
<td>Participants were randomized to receive, in addition to standard care, 30min of general balance training (CG) or 30min of sensory integrated training (EG). Intervention occurred 5d/wk for 4wk. Outcomes were assessed at baseline and 4wk.</td>
<td>Muscle Activity; Limits of Stability (LoS).</td>
</tr>
<tr>
<td>Shin &amp; Song (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>N=24</td>
<td></td>
<td></td>
<td>EG: N=12; Mean age=57.75±14.03yr; Gender: unspecified. CG: N=12; Mean age=59.25±9.75yr; Gender: unspecified.</td>
<td>The EG received smartphone-based visual feedback trunk control training (SPVFCT), and the CG received usual care. Both groups completed 5 80min sessions/wk of conventional rehabilitation for 4wk. The EG received additional 20min sessions/wk for 4wk. Assessments were conducted at baseline, and</td>
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</table>
Outcomes: Timed-Up and Go Test (TUG); static sitting balance under both eyes close and eyes open conditions; Modified Functional Reach Test (mFRT) forward and affected side; Trunk Impairment Scale (TIS).

3. The change from baseline to post-intervention on the TUG was significantly different between the two groups (p<0.001).

4. The change from baseline to post-intervention on the TIS was significantly different between the two groups (p=0.002).

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<tbody>
<tr>
<td>France</td>
<td>20 hemiplegic stroke patients with axial postural disturbances were randomized to either a device group (DG), in which patients followed experimental program for 1 hour a day using the Bon Saint Come device for axial postural rehab, or to a control group, in which patients received conventional neurorehab for 2 hours a day for 1 month (CG). After an experimental period, all patients received 2 months of conventional neurorehab for 2 hours a day. Patients were assessed on days 0, 30 and 90 by a battery of postural test, gait evaluation, the Bells neglect test and FIM instrument.</td>
<td>30 chronic stroke patients admitted for a late 4-week course of inpatient rehabilitation were randomly assigned to receive either conventional rehab or conventional rehab + a balance training with a kinaesthetic ability training (KAT) device. Outcome measures, assessed before and after treatment, included kinaesthetic ability training static and dynamic balance indices, balance and lower extremity sub scores of the Fugl-Meyer Stroke Assessment Instrument (FMA) and total motor and locomotor sub item scores of the FIM.</td>
<td>44 patients admitted for inpatient rehabilitation who were able to walk for 10 m (independently or with assistance) were randomized to either a control or balance trainer device group. Patients trained for 20 min per day, 5 days per week for 4 weeks and received an additional 25 min of physiotherapy. Balance was assessed by the Berg Balance Scale (BBS), one-leg standing, Timed Up and Go (TUG) Test and 10 m walk before and after treatment.</td>
<td>40 patients with chronic stroke were randomized to receive balance training on a newly developed device called the “Balance Control Trainer” (BCT) (n=20), 20min/day, 5days/week for 4 weeks, in addition to conventional physiotherapy. The control group only received conventional PT for 4 weeks (n=20). Outcomes assessed at 2 and 4 weeks.</td>
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<tr>
<td>RCT</td>
<td>On day 30 postural (Trunk Control Test and the Upright Equilibrium Index) and neglect tests improved significantly in DG vs. CG. A significant benefit remained at day 90. Gait improved earlier in DG than CG. FIM scores improved equally between DG and CG.</td>
<td>The experimental group had significantly greater improvement in measures of balance including static and dynamic balance index and FMA balance score than the control group. No between-group differences were detected in subscore of FMA, total motor and locomotor subscores of FIM. There were significant improvements in balance subscores of FMA, static and dynamic balance indexes in the experimental group and in sub-item scores of FIM and lower extremity scores of FMA within both groups.</td>
<td>There was significant improvement in mean BBS scores (P&lt;0.001), TUG (P&lt;0.001) and 10 m walk (P=0.001) in both the groups, but no significant differences between groups. Within both groups, significantly fewer subjects needed assistance of a physiotherapist for the 10 m walk and the TUG test by the end of the study (P=0.016).</td>
<td>At 2 weeks significant between group differences favoring the BCT group were seen on the 10mwt (p&lt;0.05), TUG (p&lt;0.05) and BBS (p&lt;0.05). At 4 weeks, there continued to be a significant between-group difference on the above outcome measures. In addition a significant difference favoring the BCT group was seen on the FAC (p&lt;0.05). No significant between group differences</td>
</tr>
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</table>
were Functional Ambulation Categories (FAC), 10 meter walk test (10mwt), Berg Balance Scale (BBS), Modified Barthel Index (MBI), Timed Up and Go (TUG) and Manual muscle testing (MMT).

**Ordahan et al. (2015)**

Turkey  
RCT  
PEDro=5  
TPS_{EG}=90.1±24.6d  
TPS_{CG}=84.6±27.6d  
N_{Start}=50  
N_{End}=50  

**Population:** Experimental group (EG; N=25): Mean age=566.7±8.9yr, Gender: Males=15, Females=10. Control group (CG; N=25): Mean age=57.6±9.4yr, Gender: Males=16, Females=9.  
**Intervention:** Participants were randomly assigned to received 30 sessions of conventional rehabilitation program (CG) or training with a balance trainer in addition to conventional rehabilitation program (EG). Outcomes were assessed at baseline and post-treatment.  
**Outcomes:** Motor and Cognitive Functional Independence Measure (FIM); Berg Balance Scale (BBS); Timed-Up-and-Go Test (TUG).

1. Both EG and CG groups showed a significant improvement in FIM Motor (p=0.039 and p=0.038, respectively), FIM Cognitive (p=0.028 and p=0.034, respectively), BBS (p=0.018 and p=0.020, respectively), and TUG (p=0.018 and p=0.020, respectively).
2. The EG group showed a significantly greater improvement in BBS (p=0.038) and TUG (p=0.025) compared to the CG group.
3. There was no significant difference in improvement between groups in FIM Motor (p=0.451) or FIM Cognitive (p=0.254).

**Braun et al. (2016)**

Germany  
RCT  
PEDro=8  
TPS_{EG}=30±22d  
TPS_{CG}=29±19d  
N_{Start}=28  
N_{End}=28  

**Population:** Experimental Group (EG, N=14): Mean age=61±16yr; Gender: Males=7, Females=7. Control Group (CG; N=14): Mean age=60±14yr; Gender: Males=5, Females=9.  
**Intervention:** The EG underwent usual care plus additional dynamic standing practice on a modified standing frame, and the CG received usual care with static standing training. Training was given over a period of 5wk, 3-5x/wk, in 30min sessions. Outcomes were assessed at baseline (T0), post-intervention (T1), and at a 2wk follow-up (T2).  
**Outcomes:** Functional Ambulation Category (FAC); Berg Balance Scale (BBS); De Morton Mobility Index (DMMI); Functional Independence Measure (FIM).

1. The EG did significantly better than the CG on the BBS at T1 (p=0.012) and T2 (p=0.042).
2. The EG did significantly better than the CG on the FAC at T1 (p=0.006), and T0 compared to T1 (p=0.022).
3. The EG did significantly better than the CG on the DMMI at T1 (p=0.018) and T2 (p=0.038).
4. The EG did significantly better than the CG on the FIM at T1 (p=0.006) and T2 (p=0.005).

**Stretching Exercises**

**Au-Yeung et al. (2009)**

China  
RCT  
PEDro=6  
TPS=6mo  
N=136  

136 subjects >6 months after stroke were randomly assigned to a control group (n = 62) practicing general exercises or a Tai Chi group (n = 74) for 12 weeks of training. Each week, 1 hour of group practice was supplemented by 3 hours of self-practice. The short-form of Tai Chi consisting of 12 forms that require whole-body movements to be performed in a continuous sequence was used. Assessments were conducted at baseline, 6 weeks (mid-program), 12 weeks (end-program), and 18 weeks (follow-up). The 3 outcome measures were (1) dynamic standing balance evaluated by the center of gravity (COG) excursion during self-initiated body leaning in 4 directions, (2) standing equilibrium evaluated in sensory compared with the controls, the Tai Chi group showed greater COG excursion amplitude in leaning forward, backward, and toward the affected and nonaffected sides (P < .05), as well as faster reaction time in moving the COG toward the nonaffected side (P = .014) in the end-program and follow-up assessments. There were no significant differences between groups at follow-up on any of the other outcomes.
challenged conditions, and (3) functional mobility assessed by Timed-up-and-go score.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Start/End</th>
<th>Population</th>
<th>Interventions</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schmid et al. (2012)</td>
<td>United States</td>
<td>RCT</td>
<td>6</td>
<td>Chronic</td>
<td>N=47</td>
<td>47 patients with chronic stroke were randomized to receive either hour-long, biweekly yoga sessions for 8 weeks (n=37) or no therapy (wait list control group n=10). Outcomes assessed at baseline and 8 weeks included the Berg Balance Scale (BBS), the 12-item Activities-specific Balance Confidence Scale, a yes/no fear of falling question, and the stroke-specific quality of life scale (SSQOL).</td>
<td>After 8 weeks, the intervention group experienced statistically significant improvements in balance (P&lt;0.001). Significant improvements were also found for individuals in the intervention group who had baseline impairments in balance (P&lt;0.001). No significant differences in balance self-efficacy, fear of falling or SSQOL from baseline to 8 weeks were found in the yoga group. No significant differences in any outcome measure were found in the control group. Between group differences were not tested due to sample size limitations.</td>
<td></td>
</tr>
<tr>
<td>Immink et al. (2014)</td>
<td>Australia</td>
<td>RCT</td>
<td>6</td>
<td>EG</td>
<td>N=11</td>
<td>Population: Yoga Intervention (N=11): Mean age=56.1±13.6yr Gender: Males=6, Females=5. Control Intervention (N=11): Mean age=63.2±17.4yr Gender: Males=3, Females=8. Interventions: The EG received a yoga intervention. The CG received no treatment. Outcomes: Berg Balance Scale (BBS); Comfortable Gait Speed (CGS) test; the Two-Minute Walk Distance (2MWD) test.</td>
<td>1. There were no significant main effects or interactions for MAS and BBS outcomes. 2. There was a significant main effect of time for 2MWD (t = -2.12, p =0.046, ICC =0.94). However, the post-hoc analysis revealed no significant changes in 2MWD scores for either group. 3. There were no significant main effects or interactions in the analysis of CGS velocities (ICC=0.94). 4. There were no significant main effects of interactions in the analysis of CGS velocities (ICC=0.94).</td>
<td></td>
</tr>
<tr>
<td>Kim et al. (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>Chronic</td>
<td>N=22</td>
<td>Population: Experimental Group (EG; N=11): Mean age=53.45±11.54yr; Gender: Males=7, Females=4. Control Group (CG; N=11): Mean age=55.18±10.20yr; Gender: Males=6, Females=5. Intervention: Patients were randomized to receive physiotherapy alone (CG) or with tai chi (EG). Tai chi included 10 different movements and was performed 60min/d, 2d/wk for 6wk. Outcomes were assessed before and after treatment. Outcomes: Functional Reach Test (FRT); Timed Up &amp; Go Test (TUGT); Dynamic Gait Index (DGI); 10-Metre Walk Test (10MWT); Sway.</td>
<td>1. EG significantly improved on FRT, TUGT, DGI, and 10MWT after treatment, while CG did not significantly improve on any outcome. EG showed significantly greater improvements on all outcomes compared to CG. 2. EG significantly improved in sway length and velocity, both with eyes open and closed, after treatment. CG only improved in sway velocity with eyes open and sway length with eyes closed after treatment. On all parameters, EG showed significantly greater improvement than CG.</td>
<td></td>
</tr>
<tr>
<td>Lim et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>Chronic</td>
<td>N=19</td>
<td>Population: Experimental Group (EG, N=10): Mean age=66.80±5.7yr; Gender: Males=5, Females=5. Control Group (CG; N=9): Mean age=61.11±6.6yr; Gender: Males=5, Females=4. Intervention: The EG received a Pilates training program 3x/wk for 8wk. The CG did not receive any exercise or treatment. Outcomes were evaluated before and after intervention. Outcomes: Anterior-posterior centre of pressure range and velocity; medial-lateral centre of pressure range and velocity.</td>
<td>Significant differences were observed in all dynamic and static balance parameters, including anterior-posterior and medial-lateral centre of pressure range and velocity.</td>
<td></td>
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</tbody>
</table>

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<table>
<thead>
<tr>
<th>Aquatic Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Noh et al.</strong> (2008) South Korea RCT PEDro=4 TPS&lt;6mo N=25</td>
</tr>
<tr>
<td>25 ambulatory chronic stroke patients were randomized to an 8-week (3days/wk x 1hr) exercise program - either aquatic therapy consisting of Ai Chi and Halliwick methods, which focused on balance and weight-bearing exercises or conventional therapy who performed gym exercises. The primary outcome measures were Berg Balance Scale score and weight-bearing ability, as measured by vertical ground reaction force during four standing tasks (rising from a chair and weight-shifting forward, backward and laterally) assessed before and after treatment. Secondary measures were muscle strength and gait.</td>
</tr>
<tr>
<td>1. The aquatic therapy group attained significantly greater improvements in Berg Balance Scale scores (7.6 vs. 2.02 points, p&lt;0.05), forward and backward weight-bearing abilities of the affected limbs, and knee flexor strength. There were no significant changes in the other measures between the two groups.</td>
</tr>
<tr>
<td><strong>Han et al.</strong> (2013) Korea PCT No Score TPSUG=15.2±5.1mo TPSLG=16.1±5.4mo NStart=62 NEnd=60</td>
</tr>
<tr>
<td><strong>Population</strong>: Underwater exercise group (UG; N=31): Mean age=56.1±7.3yr; Gender: Males=15, Females=16. Land exercise group (LG; N=31): Mean age=56.6±10.0yr. Gender: Males=13, Females=18.</td>
</tr>
<tr>
<td><strong>Intervention</strong>: The underwater group exercise group performed underwater exercise using wonder boards in a pool. The land exercise group performed exercise using balance mats.</td>
</tr>
<tr>
<td><strong>Outcome</strong>: Balance ability; Joint position sense errors; sway area (eyes open and closed): Berg Balance Scale (BBS); Joint position sense test.</td>
</tr>
<tr>
<td>1. For both groups, there were statistically significant within-group differences recognized by joint position sense errors (p&lt;0.05).</td>
</tr>
<tr>
<td>2. Between-group differences were statistically significant for the joint position sense errors, as indicated by a greater change in the UG than the LG (p&lt;0.05)</td>
</tr>
<tr>
<td>3. For both groups, there were statistically significant with-group differences for sway area, recognized by a decrease in sway area (eyes open and closed) (p&lt;0.05).</td>
</tr>
<tr>
<td>4. Between-group differences were statistically significant for the sway area (eyes open and closed), more indicated by a greater change in the UG than the LG (p&lt;0.05).</td>
</tr>
<tr>
<td>5. In both groups, there were statistically significant within-group differences for balance recognized; this was indicated by an increase in the Berg Balance Scale (BBS) (p&lt;0.05).</td>
</tr>
<tr>
<td>6. Between-group differences were statistically significant for the UG than the LG for balance (BBS), more indicated by a greater change in the UG than the LF (p&lt;0.05).</td>
</tr>
<tr>
<td><strong>Tripp et al.</strong> (2014) Germany RCT PEDro=8 TPS=51.9±37.7d TPS=39.0±27.9d NStart=30 NEnd=27</td>
</tr>
<tr>
<td><strong>Population</strong>: Halliwick-Therapy group (N=14): Mean age= 64.8±15.0yr; Gender: Males=9, Females=5. Control Group (CG; N=16): Mean age=65.0±15.1yr; Gender: Males=10, Females=6.</td>
</tr>
<tr>
<td><strong>Intervention</strong>: The Halliwick-Therapy group received treatment over a period of 2 weeks, which included 45 mins of aquatic therapy 3x/wk and a conventional physiotherapeutic treatment 2x/wk. The CG received 5 sessions of standard physiotherapy per week over a period</td>
</tr>
<tr>
<td>1. Both groups demonstrated statistically significant within-group improvements in BBS (p&lt;0.05).</td>
</tr>
<tr>
<td>2. There were also statistically significant within-group differences demonstrated by both groups for secondary outcome measures (FRT and FAC) (p&lt;0.05).</td>
</tr>
<tr>
<td>3. There were no statistically significant differences in BBS, FAC, and FRT between groups as indicated by their mean values.</td>
</tr>
</tbody>
</table>

*Note: the article states that changes in BBS by 6
9. Mobility and the Lower Extremity

of two weeks and 45 mins per treatment session.  
**Outcomes:** Berg Balance Scale (BBS); Functional reach, functional gait ability and basic functional mobility.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Jiejiao et al.</strong> (2012)</td>
<td>China</td>
<td>RCT</td>
<td>8</td>
<td>&gt;1yr</td>
<td>92</td>
<td>92 patients, at least one year post stroke, were randomized to receive either cognitive dual task training (balance training +cognitive training) or conventional balance training. Both groups received training 5 times/week, for 40 minutes over a period of 8 weeks. The Biodex balance system was used to assess center of pressure parameters during static testing with eyes open and closed, pre and post intervention. After 8 weeks, there were significant differences between groups favoring the dual task training group, for mediolateral (p=0.004) and anteroposterior (p=0.000) sway distance with eyes open, and mediolateral sway distance with eyes closed (p=0.010).</td>
</tr>
<tr>
<td><strong>Seo et al.</strong> (2012)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td>&lt;6mo</td>
<td>40</td>
<td>40 patients within 6 months of a stroke event were randomized to either intervention or control group for physical therapy. Both groups first received standard physical therapy. The intervention group then received dual-task training where they were asked to move a cup of water from one side of their body to the other (using their affected and non-affected hand) while maintaining their balance on a balance pad. This intervention involved 30 minute sessions, 5 times per week for four weeks. The control group received single-task training where they were asked to maintain their balance on a balance pad for the same length and number of sessions as the intervention group. Sway area, sway path and sway velocity were all measured on the balance performance monitor system before and after the intervention. The dual-task training group experienced statistically significant decreases in sway area, sway path and max velocity from pre- to post-intervention (p&lt;0.05). Compared to the control group, the experimental group also had significantly improved outcomes for sway area and max velocity (p&lt;0.05). There were no differences in the gains made between groups for sway path (p&gt;0.05).</td>
</tr>
<tr>
<td><strong>Choi et al.</strong> (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td></td>
<td></td>
<td>Population: Experimental Group (EG; N=10): Mean age=64.8±10.5yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=54.6±11.8yr; Gender: Males=6, Females=4. Intervention: The EG preformed dual-task training, and the CG used a balance board for balance training. Training was 30min, 5x/wk for 4wk. All participants also received conventional training for the same amount of time as the intervention. Outcomes were measured at baseline and after the intervention. Outcomes: Berg Balance Scale (BBS); Mini-Mental State Examination (MMSE); Fugl-Meyer Assessment (FMA); Korean-Modified Barthel Index (KMBI). No significant differences were observed between the EG and CG on the BBS, MMSE, FMA or K-MBI.</td>
</tr>
</tbody>
</table>
9.2.2 Falls Prevention

Table 9.2.2.1 Summary of Study Examining a Falls Prevention Program

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richards et al. (1993) Canada</td>
<td>Single-blind RCT</td>
<td>PEDro=6</td>
<td>TPS&lt;13d</td>
<td>N=27</td>
<td>156 stroke patients, at high risk of falls were randomized into a tailored multifactorial falls prevention group or the control group which consisted of usual care. The falls prevention program consisted of usual care, an individualized home based exercise program, falls risk strategies, education, and injury risk minimization strategies. The primary outcomes were the rate of falls and proportion of fallers. Secondary outcome measures included the number of injurious falls, falls risk, participation, activity, leg strength, gait speed, balance, and falls efficacy.</td>
<td>The results showed that the intervention group was no more effective than usual care in reducing falls in stroke patients who are at high risk of falls. The primary outcome measures: Fall rates between groups (intervention group had 1.89 falls/person-year, and the control group had 1.76 falls/person-year, incidence rate ratio=1.10, P=0.74), proportion of fallers between groups (risk ratio=.83, (95% CI=0.6-1.14), injurious fall rate (intervention 0.74 injurious falls/person-year, control 0.49 injurious falls/person-year, incidence rate ratio=1.57, P=0.25). No significant differences between groups were identified in the secondary outcome measures.</td>
</tr>
</tbody>
</table>

9.3 Gait Retraining

9.3.1 Task-Specific Training

Table 9.3.1.1 Summary of Studies Examining Task-Specific Training

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Richards et al. (1993) Canada</td>
<td>Single-blind RCT</td>
<td>PEDro=6</td>
<td>TPS&lt;13d</td>
<td>N=27</td>
<td>27 patients randomized to receive one of three therapies: 1) Early intensive therapy incorporating the use of a tilt table, resisted exercises and treadmill, beginning ~8 days post stroke, for 1.7 hrs/day x 5 weeks (experimental); 2) Early conventional therapy included traditional approach with therapy beginning ~9 days post stroke, for 1.8 hrs/day x 5 wks (control 1); or 3) Conventional therapy beginning 13 days post stroke, 0.72 hrs x 5 wks (control 2).</td>
<td>At week 6, gait speed in the 2 control groups was similar and lower than the experimental group. By months 3 and 6, the gait speed between all groups was similar.</td>
</tr>
<tr>
<td>Kwakkel et al. (1999) Netherlands</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&lt;14d</td>
<td>N=101</td>
<td>101 patients were randomized 14 days following stroke to receive one of 3 therapies: 1) arm training, 2) leg training or 3) basic rehabilitation only. Leg and arm treatments were applied for 30 min 5 days/week x 20 weeks. All patients received basic rehabilitation.</td>
<td>Patients in the leg-training group (n=31) had higher median scores compared to the control group (n=37) for ADL ability (19 vs. 16), walking ability, assessed by the Functional Ambulation Categories (4 vs. 3), and dexterity (2 vs.0).</td>
</tr>
<tr>
<td>Kwakkel et al. (2002)</td>
<td>Follow-up study to Kwakkel et al. 1999. Evaluations</td>
<td></td>
<td></td>
<td></td>
<td>There were no significant between group</td>
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<tr>
<td>Country</td>
<td>Study Name</td>
<td>Description</td>
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<tr>
<td>Netherlands</td>
<td>[Blennerhassett &amp; Dite (2004)]</td>
<td>30 stroke patients were randomized to either an Upper Limb or Mobility group. All subjects received their usual rehabilitation and an additional session of task-related practice using a circuit class form for 4 weeks. Outcome measures were assessed pre- and post-treatment and at six months and included three items of the Jebsen Taylor Hand Function Test (JTHFT), two arm items of the Motor Assessment Scale (MAS), and three mobility measures, the Timed Up and Go Test (TUGT), Step Test, and Six Minute Walk Test (6MWT). The Mobility group demonstrated greater gains than the Upper Limb group (between-group differences in the 6MWT of 116.4 m, Step Test 2.6 repetitions, and TUGT -7.6 sec).</td>
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<tr>
<td>Australia</td>
<td>[Glasgow Augmented Physiotherapy Study (GAPS) group (2004)]</td>
<td>A multisite (3 centre) single-blind randomized controlled trial (RCT) comparing the effects of augmented physiotherapy with normal physiotherapy on the recovery of mobility after stroke. 70 stroke patients admitted to hospital, able to tolerate and benefit from mobility rehabilitation were randomized to receive twice the amount of physiotherapy compared to the control group. Primary outcomes were mobility milestones (ability to stand, step and walk), Rivermead Mobility Index (RMI) and walking speed. The augmented therapy group received more direct time with therapists (62 vs. 35 min/day) and were more active (8.0% versus 4.8% time standing or walking) than normal therapy controls. There were trends favouring the augmented group in the outcomes of achievement to independent walking earlier, and higher RMI scores at three months. However, there was no significant difference in any other outcome.</td>
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<tr>
<td>Canada</td>
<td>[Salbach et al. (2004)]</td>
<td>91 community-dwelling subjects with a residual walking deficit within one year of a first or recurrent stroke were randomized to an intervention group which comprised 10 functional tasks designed to strengthen the lower extremities and enhance walking balance, speed and distance or to a control intervention focusing on upper extremity activities, 3 days a wk x 6 wks. The main outcomes assessed were 6-minute walk test (SMWT), 5-m walk (comfortable and maximum pace), Berg Balance Scale and timed ‘up and go’ test. Following treatment patients in the intervention group had attained achieved greater improvements on the following outcomes measures: SMWT (40 m vs. 5m); comfortable walking speed (0.14 vs. 0.03 m/s); maximum walking speed (0.20 vs. –0.01 m/s); TUG (-1.2 vs. 1.7 sec).</td>
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<tr>
<td>USA</td>
<td>[Kluding et al. (2008)]</td>
<td>16 chronic stroke subjects with hemiparesis after stroke were randomized to receive 8 sessions over 4 weeks of either functional task practice combined with ankle joint mobilizations, or functional task practice only. Outcome measures assessed before and after treatment included changes in ankle range of motion (ROM), ankle kinematics during sit-to-stand (STS) and gait, and lower-extremity weight-bearing symmetry during STS and static standing. The subjects in the intervention group gained 5.7 degrees degrees in passive ankle ROM compared with 0.2 degree degrees in the control group (p&lt;0.01). No significant changes in ankle kinematics or weight bearing during static standing were noted in either group. The control group decreased differences in weight bearing during STS by 9.5%, whereas the intervention group increased this difference by 3.37% (p=0.01).</td>
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<tr>
<td>Korea</td>
<td>[Kwon et al. (2015)]</td>
<td>Population: Experimental Group (EG, N=20): Mean age=50.70±15.16yr; Gender: Males=14, Females=6. Control Group (CG; N=20): Mean age=50.70±15.16yr; Gender: Males=14, Females=6. There is a significant improvement in the EG compared to the CG on the TUG and 6MWT from baseline to 4wk (p=0.000, p=0.000) and differences on any of the outcome measures associated with ADL or lower mobility function at 6, 9 or 12 months.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>PEDro</td>
<td>TPS</td>
<td>N Start</td>
<td>N End</td>
<td>Gender</td>
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<tr>
<td>Verma et al. (2011)</td>
<td>India</td>
<td>8</td>
<td>14.25±6.27mo</td>
<td>15.25±6.54mo</td>
<td>44</td>
<td>60</td>
</tr>
<tr>
<td>Dean et al. (2000)</td>
<td>Canada</td>
<td>5</td>
<td>39±11d</td>
<td>32±11d</td>
<td>73</td>
<td>60</td>
</tr>
<tr>
<td>Mudge et al. (2009)</td>
<td>New Zealand</td>
<td>7</td>
<td>6mo</td>
<td>60</td>
<td>64</td>
<td>60</td>
</tr>
<tr>
<td>Renner et al. (2016)</td>
<td>Netherlands</td>
<td>5</td>
<td>49+25d</td>
<td>32±11d</td>
<td>73</td>
<td>60</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>van de Port et al. (2012)</td>
<td>The Netherlands</td>
<td>RCT</td>
<td>7</td>
<td>NA</td>
<td>250</td>
<td>250</td>
<td>Patients with stroke were randomized to receive a graded task specific circuit training program (n=126) or usual outpatient physiotherapy. Circuit training involved 8 workstations designed to improve walking ability and consisted of 90 minute sessions, 2/week over 12 weeks.</td>
<td>Primary outcome (mobility sub scale of the Stroke Impact Scale; SIS) was assessed at baseline, 6, 12,18 and 24 weeks post randomization. Secondary outcomes (other domains of the SIS, Rivermead Mobility Index,Falls Efficacy Scale, Nottingham extended activities of daily living, Hospital anxiety and depression scale, Fatigue severity scale, Motricity index, 6MWT, Functional ambulation categories, TUG, 5 m comfortable walking speed, modified stairs test) were assessed at baseline, 12 and 24 weeks.</td>
<td>No significant difference between groups for primary outcome i.e. mobility subscale of the SIS. Significant between group differences favoring the intervention group (circuit training) were seen for the 6MWT (p=0.0007), 5 m comfortable walking speed test (p&lt;0.001) and modified stairs test (p=0.015) during the exercise phase. Between group differences for the 5 m walking speed test remained significant at follow up (p=0.04). No significant between group differences were found for other secondary outcomes post intervention or at follow up.</td>
</tr>
<tr>
<td>Kim et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>7</td>
<td></td>
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<td></td>
<td></td>
<td>There were no significant differences between the EG and CG on the FMA-LE, BBS, 6MWT, and the K-MBI.</td>
</tr>
<tr>
<td>Lee et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td></td>
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</tbody>
</table>
training sessions each week for 4 weeks.  

**Outcomes**: Weight-bearing footprint, anterior length in the limit of stability, posterior length in the limit of stability, surface area ellipse of Romberg, and length of Romberg before and after the training.

2. There were statistically significant between-group differences after the intervention in regard to changes in the weight-bearing footprint [post-test EG: 46.0±7.7, post-test CG: 51.0±15.2]; the anterior length in the limit of stability [post-test EG: 54.0±12.5, post-test CG: 49.0±15.2] and the posterior length in the limit of stability [post-test EG: on both the paretic and non-paretic sides, and in the surface area ellipse of Romberg.

3. There were no statistically significant differences in the length of Romberg between the two groups after the intervention.

**Park et al.** (2015)  
Korea  
RCT  
PEDro=5  
TPS=35.04±13.99mo  
NStart=24  
NEnd=24  

**Population**: Experimental group (EG; N=12). Control group (CG; N=12).  

**Intervention**: Participants were randomized to receive step-climbing exercise (EG) or stair gait exercise (CG). Both groups completed 15min of respected intervention 3x/wk for 8wk. Outcomes were assessed at baseline and 8wk.  

**Outcomes**: Muscle Strength; Time-Up-and-Go Test (TUG); Step Length.  

1. Both groups showed significant improvements in Muscle Strength, TUG, and Step Length (all p<0.05).  
2. EG group showed a significantly greater improvement in rectus femoris strength (p<0.01) compared to the CG group; however, the CG group showed a significantly greater improvement in tibialis anterior strength (p=0.01) compared to the EG group. There was no significant difference between groups in gastrocnemius strength (p=0.22).  
3. There was no significant difference between groups in TUG (p=0.07) or Step length (p=0.25).
9.3.2 Treadmill Training

Table 9.3.2.1 Summary of Studies Evaluating Treadmill Training

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liston et al. (2000)</td>
<td>UK</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&gt;6mo N=18</td>
<td>In a single blind randomized cross-over study, after a 4-week baseline period, 18 patients with residual gait impairment following ischemic stroke (&gt;6 months) received either 4 weeks of treadmill re-training or 4 weeks of conventional therapy. No use of body weight support was used.</td>
<td>No significant differences were found between therapies on spatial and temporal gait measures, Activities of Daily Living, Sit-to-Stand Test, Timed 10m walk, inked footprints-5m walk, One-leg stance test, ADL-oriented assessment of mobility, Nottingham extended ADL scale, Nine-Hole peg test.</td>
</tr>
<tr>
<td>Laufer et al. (2001)</td>
<td>Israel</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPSFloor=35.8±17.3d TPS treadmill=32.6±21.2d N=25</td>
<td>25 stroke patients were assigned to either conventional physical therapy or conventional physical therapy in addition with 15 treadmill-training sessions.</td>
<td>Patients were able to tolerate treadmill training in the early stages of their rehabilitation. Treadmill training is more effective than conventional gait training for improvement on functional ambulation, stride length and percentage of paretic single stance period and gastrocnemius muscular activity.</td>
</tr>
<tr>
<td>Ada et al. (2003)</td>
<td>Australia</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS&gt;6mo NStart=29 NEnd=27</td>
<td>29 patients living in the community after having stroke were randomized to receive 30 minutes of treadmill and over-ground walking training 3 times a week for 4 weeks or to the control group receiving a low intensity, home exercise program and regular telephone contact.</td>
<td>The 4-week treadmill and overground training program significantly improved walking speed and walking speed but did not decrease handicap compared to the control program. Gains noted in the experimental group were maintained 3 months after treatment.</td>
</tr>
<tr>
<td>Langhammer &amp; Stanghelle (2010)</td>
<td>Norway</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS treadmill=419±1034d TPS walking=349±820d NStart=39 NEnd=34</td>
<td>39 chronic, ambulatory stroke subjects admitted to a private rehab hospital were randomized to receive either 30 min of treadmill training 5x/week or to go for an30 min outdoor walk 5 days/week while they attended the facility. Outcome measures assessed before and after intervention included the 6-Minute Walk Test, a 10-metre walk test and pulse rates at rest and in activity.</td>
<td>The average number of sessions subjects in both groups participated in was 8. There were significant differences in favour of the treadmill group in Six-Minute Walk Test distance (P = 0.04), Six-Minute Walk Test speed (P = 0.03), 10-m walking speed (P = 0.03), bilateral stride length (right leg; P = 0.009, left leg; P = 0.003) and step width (P = 0.01).</td>
</tr>
<tr>
<td>Study</td>
<td>Location</td>
<td>Design</td>
<td>PEDro</td>
<td>Time Frame</td>
<td>Participants</td>
<td>Intervention</td>
</tr>
<tr>
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</tr>
<tr>
<td>Kuys et al. (2011)</td>
<td>Australia</td>
<td>RCT</td>
<td>8</td>
<td>Acute</td>
<td>30</td>
<td>Treadmill walking for 30 min, 3x/week for 6 weeks in addition to usual physiotherapy (n=15) or usual physiotherapy only (n=15).</td>
</tr>
<tr>
<td>Lau &amp; Mak (2011)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>6</td>
<td>Subacute</td>
<td>26</td>
<td>Short interval walking trials with stepwise increases in treadmill speed (speed-dependent treadmill training), following the principles of sprint training (n=15) or a control group where subjects received gait training on the treadmill at a steady speed (n=15). The 10 treatment sessions in both groups lasted 30 minutes. In addition, patients received an additional 90 minutes of rehabilitation. Outcomes included gait speed, stride length, cadence, and Berg’s Balance Score (BBS) were recorded and analysed before and after training.</td>
</tr>
<tr>
<td>Kosak &amp; Reding (2000)</td>
<td>USA</td>
<td>RCT</td>
<td>4</td>
<td>Partial body weight-supported treadmill training (PBWSTT) or to receive aggressive bracing assisted walking (ABAW). Treatment sessions of up to 45 minutes, 5 days per week given as tolerated for the duration of the inpatient stay or until patient could walk over-ground unassisted in addition, 45 minute session of functionally oriented physical therapy each day given. Time since stroke onset was 40±3 days.</td>
<td>No significant differences were found between groups on over-ground walking endurance and speed. Significant improvement and between group differences were noted in a subgroup of severely impaired patients who had received more than 12 treatments.</td>
<td></td>
</tr>
<tr>
<td>Nilsson et al. (2001)</td>
<td>Sweden</td>
<td>RCT</td>
<td>7</td>
<td>8 weeks</td>
<td>73</td>
<td>Stroke patients with residual hemiparesis and whom were within 8 weeks of stroke onset were randomized to receive walking training on a treadmill with body weight support (BWS) for 30 minutes, 5 days a week or to receive walking training according to Motor Relearning Program (MRP) on the ground for 30 minutes a day for 5 a days a week. All patients received professional stroke rehabilitation. Treatment lasted between 2 to 19 weeks.</td>
</tr>
<tr>
<td>Da Cunha et al. (2002)</td>
<td>USA</td>
<td>RCT</td>
<td>7</td>
<td>Less than 6 weeks</td>
<td>13</td>
<td>Stroke patients less than 6 weeks post stroke were randomized to receive either</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Intervention</td>
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<tr>
<td>Eich et al.</td>
<td>Germany</td>
<td>RCT</td>
<td>4</td>
<td>TPS&lt;6wk</td>
<td>13</td>
<td>Regular rehabilitation (REG) or to regular rehabilitation with supported treadmill ambulation training (STAT) for 2 to 3 weeks. The STAT group received daily gait training utilizing a treadmill with partial support of body weight instead of the 20 minutes of gait training of the REG group. Gait training for the STAT group was conducted for 20 minutes, 5 days a week. Outcomes included Functional Ambulation Category Scale, gait speed, walking distance, gait energy expenditure, and gait energy cost.</td>
</tr>
<tr>
<td>Suputtitada et al.</td>
<td>Thailand</td>
<td>RCT</td>
<td>5</td>
<td>TPS=Chronic</td>
<td>50</td>
<td>50 patients recovering from a stroke, which occurred not more than 6 weeks, previously with a Barthel Index score of 50-80 who were functional ambulators were randomized to treadmill training with minimal weight bearing support (no more than 15% of body weight) group + 30 minutes of physiotherapy or 6 weeks or to routine physiotherapy for 60 minutes daily. The primary outcome was absolute improvement in walking velocity (m/s) and capacity (m). Patients were assessed pre-test, post-test and at 12 weeks.</td>
</tr>
<tr>
<td>Sullivan et al.</td>
<td>USA</td>
<td>RCT</td>
<td>7</td>
<td>TPS=4-60mo</td>
<td>80</td>
<td>80 ambulatory stroke subjects participated in a clinical trial designed to determine the effects of combined task-specific and lower-extremity (LE) strength training to improve walking ability after stroke. The exercise interventions consisted of body-weight-supported treadmill training (BWSTT), limb-loaded resistive leg cycling (CYCLE), LE muscle-specific progressive-resistive exercise (LE-EX), and upper-extremity ergometry (UE-EX). After baseline assessments, participants were randomly assigned to a combined exercise program that included an exercise pair. The exercise pairs were: BWSTT/UE-EX, CYCLE/UE-EX, BWSTT/CYCLE, and BWSTT/LE-EX. Exercise sessions were 4 times per week for 6 weeks (total of 24 sessions), with exercise type completed on alternate days. Outcomes assessed included self-selected walking speed, fast walking speed, and 6-</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro Score</td>
<td>Treatment Duration</td>
<td>Participants</td>
<td>Intervention Details</td>
</tr>
<tr>
<td>-----------------------------------------</td>
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<tr>
<td>Yen et al. (2008)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&lt;6mo</td>
<td>N=14</td>
<td>14 patients within 6 months of stroke onset who were able to walk at least 10 m with or without assistance were randomly assigned to the experimental or control group. Participants in both groups participated in general physical therapy. Those in the experimental group received additional body weight- supported treadmill training for 4 weeks. The outcome measures assessed before and after treatment included the Berg Balance Scale (BBS) and various gait parameters.</td>
</tr>
<tr>
<td>Franceschini et al. (2009)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS&lt;6wk</td>
<td>N=97</td>
<td>97 subjects, recruited within 6 weeks of stroke onset, were randomly assigned to conventional rehabilitation plus gait training with body weight support on a treadmill (experimental group; n=52) or conventional treatment with overground gait training only (control group; n=45). All subjects were treated in 60-minute sessions every weekday for 4 weeks. Outcome measures were Motricity Index, Trunk Control test, Barthel Index, Functional Ambulation Categories, 10-meter and 6-minute Walk Tests, and Walking Handicap Scale. Assessments were made at baseline, after 20 sessions of treatment, 2 weeks after treatment, and 6 months after stroke.</td>
</tr>
<tr>
<td>Ada et al. (2010)</td>
<td>Australia</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS&lt;28d</td>
<td>N=126</td>
<td>126 acute (within 28 days of stroke onset), nonambulatory stroke patients were randomly allocated to an experimental (n=64) or a control group (n=62). The experimental group undertook up to 30 minutes per day of treadmill walking with body weight support via an overhead harness whereas the control group undertook up to 30 minutes of overground walking. The primary outcome was the proportion of participants achieving independent walking within 6 months.</td>
</tr>
<tr>
<td>Moore et al. (2010)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS=Chronic</td>
<td>N=20</td>
<td>20 chronic stroke subjects completed a randomized crossover trial evaluating additional gait training after reaching a plateau. After the last 4 weeks of outpatient physical therapy (PT) subjects either received 4 weeks of intensive Locomotor training (LT) using a treadmill with body-weight support or continued with their conventional treatment. At the end of that 4-week period, average daily stepping increased significantly following LT treatment (4,207 vs, 5,560 step/day p&lt;0.001). A significant group x time interaction effect was reported for the following variables; fastest velocity (m/s), oxygen cost (mL/kg/km) and peak treadmill speed.</td>
</tr>
</tbody>
</table>
Subjects were crossed over and received an additional 4 weeks of treatment. Outcome measures included clinical and physiological (metabolic) measures of walking overground and on a treadmill, and measures of daily stepping activity in the home and community, including during clinical PT and subsequent LT sessions.

<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Year</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yang et al. (2010)</td>
<td>2010</td>
<td>Taiwan</td>
<td>RCT</td>
<td>7</td>
<td>&lt;6mo or &gt;12mo</td>
<td>18</td>
<td>18 hemiparetic stroke patients with either short (&lt; 6 months) or long (&gt; 12 mo) onset duration were randomly assigned to receive 12 sessions of BWSTT (30 min + 20 min general exercise program, 3x/week) over 4 weeks or to a control group that received the same amount and duration of therapy provided by a general exercise program. The primary outcomes were motor threshold and map size of the abductor hallucis muscle in the ipsilesional hemisphere. The secondary outcome was Fugl-Meyer (FM) Assessment. Outcome measures were assessed before and after training. Patients in the BWSTT group experienced a significantly greater decrease of motor threshold and an increase of map size in subjects with hemiparesis of short duration. Only the expansion of the map size was noted in subjects with hemiparesis of long duration. Patients both with long and short duration of onset who received BWSTT gained significantly more FM points compared with patients in the control group.</td>
</tr>
<tr>
<td>Duncan et al. (2011)</td>
<td>2011</td>
<td>USA</td>
<td>RCT</td>
<td>7</td>
<td>Early treadmill=2mo, Late treadmill=6mo, Home=2mo</td>
<td>408</td>
<td>408 patients with stroke onset of 2 months were randomized to undergo one of 3 training regimens: early treadmill training with partial body-weight support (within 2 months of stroke) (n=139), late treadmill training with partial body-weight support (6 months after stroke) (n=143) and a home-based exercise program (n=126). All programs consisted of 90 min sessions, 3x/week for 12 to 16 weeks. The primary outcome was the proportion of patients with improved level of functional walking, defined as the ability to walk independently at a speed of &gt;0.4 m/s (severe impairment at baseline) or &gt;0.8 m/s (moderate baseline impairment) at 1 year. Secondary outcomes included gait speed, Fugl-Meyer Assessment, Berg Balance Scale, activities of daily living and items on the stroke Impact Scale. At one-year, 52% of all patients had improved functional walking ability. There was no difference in the proportion of improvement was found among the 3 groups. There were no differences among the groups on any of the secondary outcomes. The lack of difference persisted after adjusting for initial impairment.</td>
</tr>
<tr>
<td>Hoyer et al. (2012)</td>
<td>2012</td>
<td>Norway</td>
<td>RCT</td>
<td>7</td>
<td>TPS&lt;6mo</td>
<td>60</td>
<td>60 stroke patients within 6 months following a stroke were randomized to Treadmill training with body weight support (TTBWS) (30 mins of treadmill training + 30 mins of functional training per session) or traditional overground walking (OG) (30 mins of intensive gait training + 30 mins of functional training per session). Both groups received 30 sessions over a minimum of 10 weeks. The primary outcome measure was the Functional Ambulation Categories (FAC). There was no significant difference between groups in terms of all outcomes assessed post intervention and at follow up assessments. Both groups demonstrated improvement from baseline FAC: change scores of 1.7 (TTBWS) vs 1.4 (OG). 10MWT: TTBWS improved from 0.22m/s to 0.40m/s at 11 weeks, OG group improved from 0.20m/s to 0.36 m/s. 6MWT: Change scores of 67 m (TTBWS) vs 56 m (OG).</td>
</tr>
</tbody>
</table>
Secondary outcome measures included the 10 meter timed walk (10MWT), 6 minute walk test (6MWT), FIM, EU walking. Assessments were conducted post intervention, at 5 and 11 weeks.

MacKay-Lyons et al. (2013)  
Canada  
RCT  
PEDro=8  
TPS<1mo  
N=50  
50 stroke patients within one month following a stroke were randomized to a 12-week body weight supported treadmill training (BWSTT) program (intervention) or usual care (UC; comparison/control). BWSTT and UC programs were balanced in terms of exposure and consisted of 60-min sessions, 5 days a week for 6 weeks, followed by three 60-min session per week for 6 weeks (48 sessions total). Primary outcome measures included cardiovascular fitness (peakVO₂) and walking function (6-minute walk test; 6MWT). Secondary outcome measures included balance (Berg Balance Scale; BBS) and motor impairment of the paretic lower extremity (the Chedoke-McMaster Stages of Recovery (CMSR) Leg and Foot). All measures were collected at baseline, completion of training (3-months), and at 6- and 12-month follow-ups.

1. Significant Group x Time interactions were found for peakVO₂ and 6MWT measures. With respect to peakVO₂, there were no significant changes for the UC group, however significant changes (increases) occurred for the BWSTT group at 3-, 6-, and 12-months compared to baseline. Both the BWSTT and UC groups showed significant improvements over baseline at post-training for their 6MWT distance (m). No significant Group x Time interactions were found for BBS and CMSR Leg, however a significant Group x Time interaction was found for CMSR Foot. The BWSTT group exceeded CMSR Foot baseline values at post-training, 6- and 12-month follow-ups.

Ribeiro et al. (2013)  
Brazil  
RCT  
PEDro=5  
TPSGroup1=19.77mo  
TPSGroup2=33.36mo  
NStart=25  
NEnd=23  
Population: Group 1 (N=9): Mean Age=58.33yr; Group 2 (N=18): Mean Age=56.45yr.  
Intervention: All patients received treatment for 30min/d, 3d/wk for 4wks. Group 1 received proprioceptive neuromuscular facilitation training consisting of waist disassociation movements and sitting and standing where the therapist controls and resists pelvic movement during weight transfer. Group 2 received treadmill training with partial body-weight support. Training involved using a harness (initially bears 30% of weight, decreased as patients progress) while walking at a comfortable pace for 20min.  
Outcomes: Walking ability, neurological severity, muscle tone of the affected lower limb, ability to perform activities of daily living, motor recovery and gait kinematics: Functional ambulation category (FAC-assesses ability in terms of support required), national institute of health stroke scale (NIHSS), modified Ashworth scale (MAS), stroke rehabilitation assessment of movement (STREAM-assesses through.
voluntary movement and basic mobility), motor component of the functional independence measure (FIM) and kinematic analysis of the affected leg gait as patients walk 10m.

**Middleton et al. (2014)**

**USA**

**RCT**

**PEDro=6**

**TPS**<sub>EG1</sub>=50.41mo

**TPS**<sub>EG2</sub>=29.03mo

**N<sub>Start</sub>=50**

**N<sub>End</sub>=31-43**

**Population:** Experimental Group (EG1; N=23): Mean age=61.39±15.69yr; Gender: Males=14, Females=9. Experimental Group 2 (EG2; N=20): Mean age=60.70±11.43yr; Gender: Males=16, Females=4.

**Intervention:** Participants in EG1 were randomly allocated to the body weight-supported treadmill training (BWSTT) group and received 1 hour of treadmill training in addition to 2 hours of balance activities, strength activities, coordination training, and range of motion activities, totalling to 3 hours of training. Participants in EG2 received 3 hours of intermixed overground gait activities, balance activities, strength activities, coordination training, and range of motion activities. Further, they received the intervention for 3 hours for 10 consecutive weekdays for a total of 30 hours. All participants were assessed at baseline before the training, at pre-test (1 day before intervention), at post-test (1 day after completion), and at follow-up (52-153 days after completion).

**Outcomes:** Gait, balance, mobility: step length differential (via GAITRite); 3 meter walk test (3MWT); 6 minute walk test (6mWT); Berg Balance scale (BBS), dynamic gait index (DGI); activities specific balance confidence scale (ASBCS); single limb stance (SLS); Timed Up-and-Go test (TUG) Fugl-Meyer Scale Lower extremity subscale; stroke impact scale (SIS).

1. No significant differences were found between groups on any of the outcome measures assessed either immediately after training (pre-test to post-test) or over the long term (pre-test to follow-up) [mean difference data between the different time points is presented in table format].

2. Since there was a lack of significant difference observed between the groups, the data was combined and analyzed across time points. A significant difference between pre-test to post-test was found on the 3MWT (p=0.005), TUG (p<0.001), BBS (p<0.0001), ASBCS (p=0.001), DGI (p<0.0001), Fugl-Meyer-LE (p=0.00), and on the SIS (p=0.002). Of these measures, several remained significant from pre-test to follow-up: ASBCS (p=0.04), DGI (p=0.001), Fugl-Meyer-LE (p=0.01), and the SIS (p=0.01).

**DePaul et al. (2015)**

**Canada**

**RCT**

**PEDro=8**

**Med TPS**<sub>MLWP</sub>=18.0wk

**Med TPS**<sub>BWSTT</sub>=18.5wk

**N<sub>Start</sub>=71**

**N<sub>End</sub>=58**

**Population:** Motor learning walking program group (MLWP; N=35): Mean age=66.40±10.98yr; Gender: Males=21, Females=14. Body-weight-supported treadmill training group (BWSTT; N=36): Mean age=69.03±12.26yr; Gender: Males=22, Females=14.

**Intervention:** Participants were allocated to either the experimental motor-learning walking program (MLWP) or to the body-weight-supported treadmill program (BWSTT). The MLWP group practiced 7 core walking exercises (i.e. short walks; longer distance; steps, curbs, slopes; obstacle

1. There was no change in comfortable gait speed at T2 between the two groups (ΔM=0.002 m/s, 95% CI: -0.112, 0.117).

2. There was no significant change between the two groups at T2 or at T3 on the 6mWT, Functional Balance Tests scores, Functional Balance Test time, ASBCS, LSA, SIS global recovery, SIS ADL, SIS mobility, and SIS participation.
avoidance; transitions; changes in centre of gravity; change in direction), where upon successful completion of each, the challenge level was adjusted. In the BWSTT group, patients practiced high repetitions of near-normal gait pattern while supported over a treadmill. Both intervention groups were offered 15 sessions over 5 weeks. Patients were assessed at 1 week prior to initiating the training (T1), at 1 week follow-up after the completion of the training (T2), and at 2 mo after training (T3).

**Outcomes:** 5-meter walk test (5MWT), 6-minute walk test (6mWT), Functional Balance Test; Activities-specific Balance Confidence Scale (ASBCS); stroke impact scale (SIS); Life space assessment (LSA).

**Population:** Experimental Group (EG; N=10): Mean age=59.1±12.5yr; Gender: Males=8, Females=2. Control Group (CG; N=8): Mean age=59.8±6.3yr; Gender: Males=5, Females=3.

**Intervention:** Participants were randomly assigned to either the treatment group and received body weight-supported treadmill training (BWSTT) for 20 minutes/session, for 3 sessions/week, for 4 weeks, or to the CG and did not perform BWSTT but rather continued the same rehabilitation regimen that they were on prior to participation in the study. The study period was 12 weeks divided into a baseline phase of 4 weeks (BLp) and an intervention or non-intervention phase (for the CG) of 4 weeks (INT), and an observational phase of 4 weeks (OBV).

**Outcomes:** Gait speed; cadence; step length; Timed Up-and-Go test (TUG).

**Takao et al.** (2015) Japan

<table>
<thead>
<tr>
<th>RCT</th>
<th>PEDro=4</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPS&lt;sub&gt;EG&lt;/sub&gt;=35.3mo</td>
<td></td>
</tr>
<tr>
<td>TPS&lt;sub&gt;CG&lt;/sub&gt;=39.3mo</td>
<td></td>
</tr>
<tr>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=18</td>
<td></td>
</tr>
<tr>
<td>N&lt;sub&gt;End&lt;/sub&gt;=18</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Population</th>
<th>Experimental Group (EG; N=10): Mean age=59.1±12.5yr; Gender: Males=8, Females=2. Control Group (CG; N=8): Mean age=59.8±6.3yr; Gender: Males=5, Females=3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>Participants were randomly assigned to either the treatment group and received body weight-supported treadmill training (BWSTT) for 20 minutes/session, for 3 sessions/week, for 4 weeks, or to the CG and did not perform BWSTT but rather continued the same rehabilitation regimen that they were on prior to participation in the study. The study period was 12 weeks divided into a baseline phase of 4 weeks (BLp) and an intervention or non-intervention phase (for the CG) of 4 weeks (INT), and an observational phase of 4 weeks (OBV).</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Gait speed; cadence; step length; Timed Up-and-Go test (TUG).</td>
</tr>
</tbody>
</table>

1. The gait speed in the treatment group improved significantly compared to the CG (p<0.05).
2. The other parameters showed no significant interaction (cadence, p=0.11; step length, p=0.14; TUG, p=0.60).
3. The gait speed was significantly correlated with cadence (r=0.78, p<0.05) and step length (r=0.74, p<0.05).

**Srivastava et al.** (2016) India

<table>
<thead>
<tr>
<th>RCT</th>
<th>PEDro=6</th>
</tr>
</thead>
<tbody>
<tr>
<td>TPS&lt;sub&gt;EG1&lt;/sub&gt;=391.80±431.10d</td>
<td></td>
</tr>
<tr>
<td>TPS&lt;sub&gt;EG2&lt;/sub&gt;=442.07±295.13d</td>
<td></td>
</tr>
<tr>
<td>TPS&lt;sub&gt;CG&lt;/sub&gt;=652.20±579.04d</td>
<td></td>
</tr>
<tr>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=45</td>
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<td>N&lt;sub&gt;End&lt;/sub&gt;=34</td>
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<table>
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<tr>
<th>Population</th>
<th>Experimental Group 1 (EG1; N=15): Mean age=44.20±11.70yr; Gender: Males=12, Females=3.  Experimental Group 2 (EG2; N=15): Mean age=47.93±9.95yr; Gender: Males=12, Females=3.  Control Group (CG; N=15): Mean age=44.40±12.31yr; Gender: Males=12, Females=3.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>EG1 received bodyweight support treadmill training, EG2 received treadmill training without bodyweight support, and the CG received overground gait training. Training was 30min/d, 5x/wk, for 4wk. Outcomes were assessed at baseline (T0), post-intervention (T1), and at a 3mo</td>
</tr>
</tbody>
</table>

1. There were no significant differences between the groups at T1 or T2 on the FAC, SSS, walking speed, or walking endurance.
follow-up (T2).

**Outcomes:** Scandinavian Stroke Scale (SSS); Functional Ambulation Category (FAC); walking speed; walking endurance.

### Other Modifications

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS EG</th>
<th>TPS CG</th>
<th>N Start</th>
<th>N End</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carda et al. (2013)</td>
<td>Italy</td>
<td>RCT</td>
<td>5</td>
<td>823.3d</td>
<td>970.4d</td>
<td>19</td>
<td>15</td>
</tr>
<tr>
<td>Bang et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>15.4mo</td>
<td>13.7mo</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Chen et al. (2014)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>7</td>
<td>2.2yr</td>
<td>2.9yr</td>
<td>15</td>
<td>15</td>
</tr>
</tbody>
</table>

**Population:** UP group (N=19): Mean age=58.26±8.41yr; Gender: unspecified. DOWN group (N=19): Mean age=54.16±12.49yr; Gender: unspecified.

**Intervention:** Participants were randomly allocated to one of two treadmill gait training groups. All participants first received 45 min/day conventional physical therapy, for 5 times/week, for 6 weeks, followed by 30 minutes of treadmill gait training each depending on their group allocation. One group received gait training on a treadmill set with uphill belt inclination of 15% (UP group), and the other received gait training on a treadmill set with a downhill belt inclination of 5% (DOWN group). All participants were assessed at baseline (T0), at the end of treatment (T1), and 3 mo follow-up (T2).

**Outcomes:** number of patients that showed gait improvement: number of patients that improved their walking speed: 6 minute walk test (6MWT); 10 meter walk test (10MWT); Timed Up-and-Go test (TUG).

1. Only the UP group showed a significant improvement from T0 to T1 on the 6MWT (p<0.05), 10mWT, and the TUG (all p<0.05).
2. Both UP and DOWN groups improved from T0 to T2 on the 6MWT and on the 10mWT (all p<0.05).
3. Between-group comparisons showed that after treatment the number of patients showing a clinically significant improvements in both the 6MWT and the 10MWT was significantly higher in patients in the DOWN group compared to the UP group (6MWT: NUP=3, NDOWN=16, p<0.001; 10MWT: NUP=4, NDOWN=11, p=0.045).

1. Both groups improved on the 10MWT, TUG, and 6MWT (both p<0.05).
2. A significant difference in improvement between the two groups was found on the TUG and on the 6MWT (both p<0.05).

1. Both groups improved turning speed toward the affected side and unaffected side, but the improvement was greater in the EG than the CG (affected side: p=0.029; unaffected side: p=0.007).
2. The EG demonstrated greater improvements
allocated to either the CG or the EG. The EG receive 30 minutes of turning-based treadmill training, while the CG received 30 minutes of regular treadmill training. The training in both groups was followed by a 10-minute general exercise program, for 12 sessions over a 4-week period. Participants were assessed the day before intervention (pre-test), the day after completing the intervention (post-test), and 30 days follow-up.

**Outcomes**: Berg Balance Scale (BBS); Limits of stability (LOS); Sensory organization test (SOT); turning speed; walking speed; stride length; cadence; temporal asymmetry ratio; spatial asymmetry ratio.

<table>
<thead>
<tr>
<th>N&lt;sub&gt;Start&lt;/sub&gt;=31</th>
<th>N&lt;sub&gt;End&lt;/sub&gt;=30</th>
</tr>
</thead>
</table>

compared to the CG in walking speed (p=0.036) and in temporal asymmetry ratio (p=0.044).

3. Compared to the CG, the EG demonstrated greater improvement on the BBS 360° turn (p=0.003), BBS total score (p=0.048), forward reaction time of LOS (p=0.0.045), forward endpoint execution of LOS (p=0.038), and equilibrium score of SOT condition 5 (i.e. absent vision, sway-reference support (p=0.036). Within each group all improvements made at posttraining were retained at follow-up (p<0.05).

4. Compared to the CG, the EG demonstrated greater improvement in the muscle strength of the hip flexors (experimental: M<sub>post</sub>=105.1; control: M<sub>post</sub>=73.5; p=0.037), hip extensors (experimental: M<sub>post</sub>=54.5; control: M<sub>post</sub>=43.9; p=0.027), hip abductors (experimental: M<sub>post</sub>=143.0; control: M<sub>post</sub>=123.6; p=0.032), and the ankle dorsiflexors (experimental: M<sub>post</sub>=81.6; control: M<sub>post</sub>=60.4; p=0.007). All improvements made at posttraining within each group were maintained at follow-up (p<0.05).

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**Kim et al.** (2014)
Korea
RCT
PEDro=5
TPS<sub>Group1</sub>=11.33mo
TPS<sub>Group2</sub>=11.00mo
TPS<sub>Group3</sub>=11.83mo
N<sub>Start</sub>=36
N<sub>End</sub>=36

**Population**: Progressive body weight supported treadmill forwards and backwards walking training (Group 1) (N=12): Mean age=51.00±14.60yr; Gender: Males=8, Females=4. Progressive body weight supported treadmill forwards walking training (Group 2) (N=12): Mean age=52.75±9.21yr; Gender: Males=8, Females=4. Progressive body weight supported treadmill backwards walking training (Group 3) (N=12): Mean age=50.25±1.69yr; Gender: Males=9, Females=3.

**Intervention**: Participants were randomly allocated to either the progressive body weight supported treadmill forwards and backwards walking training (PBWSTFBWT) group, or to the progressive body weight supported treadmill forwards walking training (PBWSTFWT) group, or to the progressive body weight supported treadmill backwards walking training (PBWSTBWT) group. The PBWSTFBWT group performed 15 minutes of forward walking and 15 minutes of backwards walking, while the PBWSTFWT and the PBWSTBWT groups performed the respective training in 30 minutes.

1. All three groups improved significantly from week 0 to week 3 on the ASL (all p<0.05), AStP (all p<0.05), ASwP (all p<0.05), ASS (all p<0.05), AST (all p<0.05), and symmetry index (all p<0.05).
2. Only the ALS remained significant from week 3 to week 6 in all groups (all p<0.05).
3. Only the ASL and the AST differed significantly between the groups at week 3 (refer to mean values above; all p<0.05).
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>TPS_IWLG</th>
<th>TPS_NLG</th>
<th>Start</th>
<th>End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Park et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td>13.47mo</td>
<td>17.86mo</td>
<td>30</td>
<td>30</td>
<td>Incremental weight loading group (IWLG; N=15): Mean age=55.07±15.14yr; Gender: Males=8, Females=7. No-load group (NLG; N=15): Mean age=50.00±13.33yr; Gender: Males=9, Females=6.</td>
<td>Participants were randomly allocated either to the incremental weight loading group (IWLG) where they performed gait training on motor-operated treadmills with a weighted sandbag, or to a control no-load group (NLG) where they performed gait training on motor-operated treadmills without sandbags. The training was performed for 30 minutes/session, for 5 sessions/week, for 8 weeks. Participants were assessed before and after the training was completed.</td>
<td>Both IWLG and NLG demonstrated significant decreases from before to after the intervention on the SA (p&lt;0.05), and on the SL (p&lt;0.05).</td>
</tr>
<tr>
<td>Tea-Woo Kim et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>12.8mo</td>
<td>13.9mo</td>
<td>24</td>
<td>24</td>
<td>Vision-blocked group (VBG; N=12): Mean age=54.00±6.2yr; Gender: Males=8, Females=4. Vision-allowed group (VAG; N=12): Mean age=56.9±7.3yr; Gender: Males=9, Females=3.</td>
<td>Participants were randomly assigned to either the vision-blocked group (VBG) or performed sideways gait training on a treadmill with eye patches on their eyes, or to the vision-allowed group (VAG) and performed the sideways gait training on a treadmill without eye patches. The gait exercise was conducted for 20 minutes, 3 times a week, for 6 weeks. Participants were assessed before and after the gait training program.</td>
<td>The VBG demonstrated significant improvements from pre- to posttreatment in the WS, SL of the affected and unaffected sides, ST of the affected and unaffected sides, FTSST, and TUG (all p&lt;0.05). This improvement was not observed in VAG.</td>
</tr>
<tr>
<td>Gama et al. (2015)</td>
<td>Brazil</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Experimental Group (EG; N=14): Mean age=52.92±9.51yr; Gender:</td>
<td></td>
<td>There was a significant improvement in the FIM, BBS, FMA-LE, and stride length in both</td>
</tr>
</tbody>
</table>

Training was carried out 6 times per week for a total of 3 weeks. Participants were assessed at baseline (week 0), after the completion of the training (week 3) and at follow-up (week 6).

**Outcomes:** Affected side step length (ASL); affected side stance phase (AStP); affected side swing phase (ASwP); affected side single support (ASS); affected side step time (AST); symmetry index.
<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kang et al. (2015)</td>
<td>No handrail group (NHG; N=10): Mean age=57.60±19.92yr; Gender: Males=8, Females=2. Front handrail group (FHG; N=10): Mean age=53.60±8.40yr; Gender: Males=6, Females=4. Bilateral handrail group (BHG; N=10): Mean age=61.60±10.45yr; Gender: Males=6, Females=4.</td>
<td>Patients were randomly allocated to one of three groups according to the use of handrails: the no handrail group (NHG), the front handrail group (FHG), and the bilateral handrail group (BHG). Patients in the NHG performed treadmill walking without holding a handrail, those in the FHG performed treadmill walking while holding the front handrails with both hands, and those in the BHG performed treadmill walking while holding the bilateral handrails with both hands. The therapy was performed for 30 minutes/day, 5 days/week, for 8 weeks.</td>
<td>1. A statistically significant change in the HM area at post-therapy between BHG and NHG was found (ΔM&lt;sub&gt;BHG&lt;/sub&gt;=28.0; ΔM&lt;sub&gt;NHG&lt;/sub&gt;=58.5, p&lt;0.05). 2. Statistically significant changes in the HL area were observed between BHG and NHG (ΔM&lt;sub&gt;BHG&lt;/sub&gt;=13.8, ΔM&lt;sub&gt;NHG&lt;/sub&gt;=41.0, p&lt;0.05), and between FHG and NHG (ΔM&lt;sub&gt;FHG&lt;/sub&gt;=74.8, ΔM&lt;sub&gt;NHG&lt;/sub&gt;=41.0, p&lt;0.05). 3. A statistically significant change between BHG and NHG was found with respect to the rear foot area (ΔM&lt;sub&gt;BHG&lt;/sub&gt;=27.7, ΔM&lt;sub&gt;NHG&lt;/sub&gt;=26.1, p&lt;0.05). 4. No other parameters were found to be significant within groups or between groups.</td>
</tr>
<tr>
<td>Na et al. (2015)</td>
<td>Experimental Group (EG; N=12): Mean age=51.3±7.3yr; Gender: Males=8, Females=4. Control Group (CG; N=12): Mean age=52.92±8.3yr; Gender: Males=9, Females=3.</td>
<td>All participants received treadmill training, but the EG also had an applied horizontal impeding force. Training was 20min/d, 3x/wk, for 8wk. Outcomes were evaluated at baseline and post-intervention.</td>
<td>1. The EG did significantly better than the CG on the stable walking speed, maximal walking speed, number of steps per minute, TUG, and BBS (p&lt;0.05). 2. There were no significant differences between the groups on the FRT from baseline to post-intervention.</td>
</tr>
</tbody>
</table>
9.3.3 Virtual Reality Training

Table 9.4.3.1 Summary of Studies Evaluating Virtual Reality Training

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treadmill Training</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yang et al. (2008) Taiwan RCT PEDro=6 TPS&gt;6mo N=20</td>
<td>20 subjects at least 6-months post stroke were assigned randomly to either the control group (n=9) or the experimental group (n=11). Subjects in the control group received the treadmill training. Subjects in the experimental group underwent the virtual reality-based treadmill training for a 3-week period. Walking</td>
<td>From pre-treatment to post treatment subjects in the experimental group improved more significantly in walking speed and community walking time. At follow-up, the experimental group maintained a significantly faster community walking speed. There were no other significant differences between the groups.</td>
</tr>
</tbody>
</table>
speed, community walking time, walking ability questionnaire (WAQ), and activities-specific balance confidence (ABC) scale were evaluated before and after treatment and at one-month follow-up.

Yang et al. (2011)
Taiwan RCT PEDro=4 TPS>6mo N=14

14 patients > 6 months post stroke were randomized to receive either virtual reality treadmill training (level walking on a treadmill with interactive VR scenes) or traditional treadmill training (level walking on a treadmill). Patients participated in 20 min sessions 3 times/week for 3 weeks. In addition they received physiotherapy and occupational therapy as was standard practice. Outcomes were assessed using a pressure mat and included center of pressure (COP) measures, bilateral limb loading symmetric index during quiet stance, sit to stand and level walking.

There was no significant difference between groups on COP related measures and symmetric index during quiet stance (p>0.05). During quiet stance the difference between groups in COP mediolateral sway was significant (p=0.038). During sit to stand transfer, symmetric index and sway excursion were significantly different between groups (p=0.028 and 0.046 respectively) favoring the VR group. During level walking there was no significant difference between groups.

Jung et al. (2012)
Korea RCT PEDro=5 TPS=6mo N=22

Patients were randomized to receive treadmill training alone (control) or with virtual reality (treatment) for 30min/d, 5d/wk for 3wk.

Both groups significantly improved on Timed Up & Go Test and Activities-Specific Balance Confidence Scale (p<0.05). The treatment group showed significantly greater improvement on both outcomes than the control group (p<0.05).

Kang et al. (2012)
Korea RCT PEDro=7 TPS=Chronic N=30

30 patients following chronic stroke participated in a 4-week (30 min/day x 3 days/week) exercise program. Patients were randomized to one of three groups; treadmill training with optic flow (TOFG) group where subjects wore a head-mounted display that simulated a street environment and enabled them to adjust the speed (n = 10), treadmill group (TG n = 10) and control group (CG n = 10). Outcomes assessed before and after treatment included the timed up-and-go test (TUG), functional reach test, 10-m walk test, and six-minute walk test.

1. Subjects in the optic flow group performed significantly better on all outcomes assessed.
2. The improvement in the mean TUG (sec) was: -5.5 (TOFG) vs. -1.5 (TG) vs. -0.4 CG (p<0.001).
3. Subjects in the TOFG and TG groups increased their functional reach significantly compared with the CG (mean: 2.78 and 2.38 vs. 0.20, p<0.001).
4. The mean improvement in gait speed (m/sec) and distance walked (m) was also significantly improvement among patients in the TOFG compared with TG and CG. 0.21 vs. 0.03 vs. 0.01, (p<0.001) and 24.5 vs. 4.7 vs. 1.80, (p<0.001) respectively.

Cho et al. (2013)
South Korea RCT PEDro=7 TPSVWTRW=288.28d TPS=312.42d NStart=16 NEnd=14

Population: Virtual walking training using real-world video recording group (VWTRW; N=7): Mean age=64.57±4.35yr; Gender: Males=3, Females=4. Control group (CG; N=7): Mean age=65.14±4.47yr; Gender: Males=4, Females=3.

Intervention: Participants were randomized to either the treatment group and performed virtual walking training on a treadmill using real-world video recording (VWTRW), or to the CG and received walking training on a treadmill without virtual reality real-world projection. All

1. Both the VWTRW and the CG improved significantly on the BBS (p<0.05), TUG (p<0.05), gait velocity (p<0.05), cadence (p<0.05), step length (p<0.05), stride length (p<0.05), and single limb support (p<0.05).
5. The VWTRW showed significantly greater improvements than did the CG on the BBS, TUG, gait velocity, and cadence (all p<0.05).
participants took part in a standard rehabilitation program in conjunction with the study intervention. The study sessions lasted 30 minutes each, completed 3 times/week, for 6 weeks. Participants were assessed at pre- and at post training.

**Outcomes:** Berg balance scale (BBS); Timed Up-and-Go test (TUG); spatiotemporal gait abilities (velocity, cadence, paretic side step length, stride length, and single-limb support period).

<table>
<thead>
<tr>
<th>Cho et al. (2014)</th>
<th>Korea RCT</th>
<th>PEDro=7</th>
<th>TPS&lt;sub&gt;EG1&lt;/sub&gt;=414d</th>
<th>TPS&lt;sub&gt;EG2&lt;/sub&gt;=460d</th>
<th>N&lt;sub&gt;Start&lt;/sub&gt;=32</th>
<th>N&lt;sub&gt;End&lt;/sub&gt;=30</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong></td>
<td>Experimental Group 1 (EG1; N=15): Mean age=65.86±5.73yr; Gender: Males=7, Females=8. Experimental Group 2 (EG2; N=15): Mean age=63.53±5.54yr; Gender: Males=8, Females=7.</td>
<td></td>
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</tr>
<tr>
<td><strong>Intervention:</strong></td>
<td>All patients participated in standard rehabilitation programs (i.e. OT, PT, neurodevelopmental treatment) in addition to the study intervention. Participants were randomly assigned to either the treadmill training based real-world video recording (TRBVR) group or to the treadmill walking training (TT) CG. The intervention and the control training lasted 30 minutes/day, for 3 days/week, over 6 weeks. Participants were assessed one-week before and one day after the intervention.</td>
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</tr>
<tr>
<td><strong>Outcomes:</strong></td>
<td>Anterioposterior postural sway velocity (AP-PSV); mediolateral postural sway velocity (ML-PSV); postural sway velocity moment (PSVM); Berg Balance Scale (BBS); Timed Up-and-Go test (TUG); single limb support period (SLSP); double limb support period (DLSP); gait cycle (GC); gait speed; step length; stride length; cadence.</td>
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</tbody>
</table>

1. Both EG1 and EG2 demonstrated a significant effect of time on the BBS, TUG, gait speed, cadence, SLSP, step length and stride length (all p-values <0.05).
2. A significant difference between the TRBVR group and the TT group were found regarding the BBS score, TUG score, gait speed, cadence, SLSP, DLSP, step length, and stride length (refer to mean difference values above; all p<0.05).
3. Significant group x time interactions were found for the BBS score (p=0.001), TUG score (p=0.001), gait speed (p=0.003), cadence (p=0.028), SLSP (p=0.026), DLSP (p=0.008), step length (p=0.024), and stride length (p=0.018).
4. No significant correlations were found between changes in postural sway and all other outcome variables.

<table>
<thead>
<tr>
<th>Kim et al. (2015)</th>
<th>Korea RCT</th>
<th>PEDro=4</th>
<th>TPS&lt;sub&gt;CG&lt;/sub&gt;=24.1±10.7mo</th>
<th>TPS&lt;sub&gt;CG&lt;/sub&gt;=30.8±11.0mo</th>
<th>N&lt;sub&gt;Start&lt;/sub&gt;=20</th>
<th>N&lt;sub&gt;End&lt;/sub&gt;=18</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong></td>
<td>Experimental Group (EG; N=10): Mean age=57.6±3.7yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=51.9±6.1yr Gender: Males=7, Females=3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention:</strong></td>
<td>The EG received gait training with constrained induced movement therapy (CIMT) for 30 minutes per session, at 3 sessions per week, for four weeks. The CG received gait training alone.</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td><strong>Outcomes:</strong></td>
<td>Trunk Impairment Scale (TIS); Limit of stability (LOS).</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. The EG showed an improvement of 28.5% in dynamic balance, as determined by the TIS, and an improvement of 34.3% in movement distances of the paretic side as determined by the LOS.
2. Compared to the CG, the EG showed greater changes in dynamic balance. There were no within group differences found in the CG for balance ability, after gait training.

<table>
<thead>
<tr>
<th>Mao et al. (2015)</th>
<th>China RCT</th>
<th>PEDro=5</th>
<th>TPS&lt;sub&gt;CG&lt;/sub&gt;=48.9±17.01d</th>
<th>TPS&lt;sub&gt;CG&lt;/sub&gt;=48.9±17.92d</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong></td>
<td>Experimental Group (EGG N=11): Mean age=58.18±11.15yr; Gender: Males=9, Females=2. Control Group (CG; N=12): Mean age=63.09±11.51yr; Gender: Males=9, Females=3.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td><strong>Intervention:</strong></td>
<td>The EG received virtual reality</td>
<td></td>
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</tr>
</tbody>
</table>

1. There were no significant differences between the EG and CG on pelvic peaks.
2. The EG improved significantly from baseline to post-intervention on pelvic tilt (p=0.038). The EG did not improve significantly on pelvic obliquity or rotation.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Treatment Details</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forrester et al. (2016)</td>
<td>USA</td>
<td>RCT</td>
<td>4</td>
<td>Treadmill training with ankle robotics</td>
<td>Pelvic peak (tilt; obliquity; rotation).</td>
</tr>
<tr>
<td>Kim et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>Virtual reality treadmill training, community ambulation training</td>
<td>TUG, ABC, 6MWT</td>
</tr>
<tr>
<td>You et al. (2005)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>Virtual reality treatment</td>
<td>Median FAC and MMAS scores</td>
</tr>
<tr>
<td>Kim et al. (2009)</td>
<td>South Korea</td>
<td>RCT</td>
<td>6</td>
<td>Virtual reality treatment</td>
<td>Berg Balance Scale scores, balance and dynamic balance angles</td>
</tr>
</tbody>
</table>

**Table:**

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forrester et al. (2016)</td>
<td>USA</td>
<td>RCT</td>
<td>4</td>
<td>35</td>
<td>26</td>
<td>Experimental Group (EG, N=14): Mean age=59.5±3.6yr; Gender: Males=9, Females=5. Control Group (CG; N=12): Mean age=56.8±3.2yr; Gender: Males=7, Females=5.</td>
<td>The EG received treadmill-integrated ankle robotics and the CG received dose-matched seated ankle robotics videogame training. Outcomes were evaluated at baseline, post-intervention, and 6wk.</td>
<td>Pelvic peak (tilt; obliquity; rotation). There were significant improvements in the EG compared to the CG on gait velocity (p=0.01), paretic single support (p=0.05), anterior-posterior impulse (p=0.02), ankle targeting speed (p=0.03), ankle target accuracy (p=0.01), dorsiflexion active range of motion (p=0.05) from baseline to 6wk.</td>
</tr>
<tr>
<td>Kim et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>30</td>
<td>27</td>
<td>Experimental Group 1 (EG1; N=10): Mean age=56.20±7.56yr; Gender: Males=4, Females=6. Experimental Group 2 (EG2; N=10): Mean age=52.00±7.272yr; Gender: Males=5, Females=5. Control Group (CG; N=7): Mean age=48.71±9.27yr; Gender: Males=5, Females=2.</td>
<td>EG1 received virtual reality treadmill training, EG2 received community ambulation training, and the CG received physical therapy. Training was 30min/d, 3x/wk, for 4wk. Assessments were done at baseline and post-intervention.</td>
<td>Timed Up and Go Test (TUG); Activities-specific Balance Confidence scales (ABC); 6 Minute Walk Test (6MWT). There is a significant group by time interaction on the TUG (p=0.037), ABC (p=0.016), and the 6MWT (p=0.046). Time had a significant effect on the TUG (p=0.003), ABC (p=0.001), and 6MWT (p=0.000). Group did not have a significant effect on the TUG, ABC, or 6MWT.</td>
</tr>
<tr>
<td>You et al. (2005)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>10</td>
<td>10</td>
<td>10 chronic stroke patients were assigned to a virtual reality (VR) treatment designed to simulate real life situations (n=5) or a no treatment control group (n=5). VR treatment was provided for 60 min/day, 5x/wk x 4 wks. Motor function was assessed by Functional Ambulation Categories (FAC) and the walking item of the Modified Motor Assessment Scale (MMAS)</td>
<td>Following treatment there was significantly greater improvement among subjects in the experimental group on the following outcome measures: Berg Balance Scale scores, balance and dynamic balance angles (ability to control weight</td>
<td>There was a statistically significant in the median FAC and MMAS scores between the groups at the end of treatment, favouring the intervention group.</td>
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<tr>
<td>Kim et al. (2009)</td>
<td>South Korea</td>
<td>RCT</td>
<td>6</td>
<td>24</td>
<td>24</td>
<td>24 chronic, hemiparetic stroke patients were randomly assigned to either an experimental group (n = 12) or a control group. Both groups underwent conventional physical therapy, 40 mins a day, 4 days a week for 4 wks. The</td>
<td>Following treatment there was significantly greater improvement among subjects in the experimental group on the following outcome measures: Berg Balance Scale scores, balance and dynamic balance angles (ability to control weight</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro</td>
<td>Study Group</td>
<td>TPS</td>
<td>N</td>
<td>Key Findings</td>
<td></td>
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<tr>
<td>Mirelman et al. (2010)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>experimental group received an additional 30 mins of virtual reality therapy each session. Balance performance was determined by the Balance Performance Monitor and Berg Balance Scale tests. Gait performance was determined by the 10-m walking test and Modified Motor Assessment Scale.</td>
<td>Chronic</td>
<td>24</td>
<td>Greater changes in velocity and distance walked were demonstrated for the group trained with the robotic device coupled with the VR than training with the robot alone. Similarly, significantly greater improvements in the distance walked and number of steps taken in the community were measured for the group that trained with robot coupled with the VR. These differences were maintained at 3 months' follow-up.</td>
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<tr>
<td>Kim et al. (2012)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td>18 patients with chronic post stroke hemiparesis were randomized to a 4 week program using a robotic gait training device with virtual reality (VR) assistance or to a robotic device only group. Training was provided 1 hr x 3x/week x 4 weeks. Patients in the VR group executed a series of exercises through foot movement to navigate a plane or a boat through a series of targets. Outcomes included number of steps/day, speed, cadence, walking strides, maximum walking speed, longest consecutive locomotion period (min) and were assessed before/after treatment and at 3 months.</td>
<td>Chronic</td>
<td>18</td>
<td>Significant improvements in the PASS and MMAS scores occurred post intervention for both groups. Overall, improvements in PASS and MMAS scores were significantly greater for individual in the VR group vs. control group. (30.30 ± 3.19 and 34.70 ± 6.20 vs. 28.00 ± 1.63 and 33.57 ± 1.51, p&lt;0.05, respectively).</td>
<td></td>
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<tr>
<td>Fritz et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
<td>8</td>
<td>15 chronic stroke (&gt; 6 month post stroke) were randomized to an intervention (gaming) or control group. Participants randomized to the gaming group were further randomized to one of two gaming systems [Nintendo Wii vs. Playstation (PS) 2]. Participants in the gaming groups performed game play 50-60min, 4 days/week, for a period of 5 weeks. Outcome measures included the Fugl-Meyer Assessment, Berg Balance Scale, Dynamic Gait Index, 6-Minute Walk Test, 3-Meter Walk Test, Stroke Impact Scale, and the Timed Up &amp; Go. All measures were collected pre- and post-intervention, in addition at 3-months follow-up.</td>
<td>TPS&gt;6mo</td>
<td>15</td>
<td>No significant differences were found between the two gaming groups so they were collapsed into one intervention group. Overall, there was no statistically significant differences between groups for any of the outcome measures.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS (mo)</td>
<td>N Start</td>
<td>N End</td>
<td>Population</td>
<td>Intervention</td>
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<td>-------------------------------</td>
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<tr>
<td><strong>Bower et al. (2015)</strong></td>
<td>Canada</td>
<td>RCT</td>
<td>4</td>
<td>12.8wk (3.9-137.8)</td>
<td>20</td>
<td>16</td>
<td>Experimental group (EG; N=8): Mean age=60.8±16.1yr; Gender: Male=5, Female=3. Control group (CG; N=8): Mean age=60.9±14yr; Gender: Male=6, Female=2.</td>
<td>Participants were randomly assigned to receive additional motion gaming rehabilitation (EG; 40min 2x/wk for 4wk) or no gaming treatment (CG). Both groups received standard inpatient or outpatient therapy.</td>
</tr>
<tr>
<td><strong>Da Silva Ribeiro et al. (2015)</strong></td>
<td>Brazil</td>
<td>RCT</td>
<td>7</td>
<td>42.1±26.9mo</td>
<td>30</td>
<td>30</td>
<td>Experimental group (EG; N=15): Mean age=53.7±6.1yr; Gender: Male=6, Female=9. Control group (CG; N=15): Mean age=52.8.7±8.6yr; Gender: Male=5, Female=10.</td>
<td>Participants were randomly assigned to receive Nintendo Wii training (EG) or conventional physical therapy (CG). Both groups underwent 60min treatment sessions 2x/wk for 2mo.</td>
</tr>
<tr>
<td><strong>Llorens et al. (2015a)</strong></td>
<td>Spain</td>
<td>RCT</td>
<td>8</td>
<td>NA</td>
<td>22</td>
<td>20</td>
<td>Experimental Group (EG; N=15): Mean age= 55.60±7.29yr; Gender: Males=10, Females=5. Control Group (CG; N=15): Mean age=55.47±9.63yr; Gender: Males=7, Females=8.</td>
<td>Twenty 45-min training sessions with the tele-rehabilitation system, conducted 3 times a week in the clinic or in the home. The CG received the intervention in-clinic while the EG received the intervention from home.</td>
</tr>
<tr>
<td><strong>Yom et al. (2015)</strong></td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>11.14mo</td>
<td>22</td>
<td>20</td>
<td>Experimental Group (EG; N=10): Mean age=64.6yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=78.1yr; Gender: Males=5, Females=5.</td>
<td>Patients were randomized to perform immersive ankle exercises (EG) or watch a film (CG) in a virtual reality environment. EG performed exercises 30min/d, 5x/wk for 6wk. Both groups received</td>
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</tbody>
</table>
conventional rehabilitation for 30 min/d, 10x/wk for 6 wk. Outcomes were assessed before and after treatment. **Outcomes**: Velocity; Cadence; Step length; Stride length, Stance time; Swing time; Double limb support; Timed Up & Go Test (TUGT); Modified Ashworth Scale (MAS); Tardieu Scale (TS).

### Bang et al. (2016)
Korea RCT PEDro=4
TPS<sub>VR</sub>=30.4±5.4mo
TPS<sub>TT</sub>=31.6±7.4mo
N<sub>Start</sub>=40
N<sub>End</sub>=40


**Intervention**: The VR group received virtual reality training using the Nintendo Wii with visual feedback, and the TT group received treadmill training. Training was 40 min, 3x/wk, for 8 wk.

**Outcomes**: Left/right weight-bearing; anterior/posterior weight-bearing; affected side stance phase; affected side swing phase; cadence.

1. The VR group did significantly better than the TT group on left/right weight bearing (p<0.05), and anterior/posterior weight-bearing (p<0.05).
2. There were no significant differences between groups on the affected side stance phase, affect side swing phase, or cadence.

### In et al. (2016)
Korea RCT PEDro=5
TPS<sub>EG</sub>=12.54±4.14mo
TPS<sub>CG</sub>=13.58±5.28mo
N<sub>Start</sub>=30
N<sub>End</sub>=25

**Population**: Experimental Group (EG; N=13): Mean age=57.31±10.53yr; Gender: Males=8, Females=5. Control Group (CG; N=12): Mean age=54.42±11.44yr; Gender: Males=7, Females=5.

**Intervention**: All participants received conventional rehabilitation for 30 min. The EG also received lower limb virtual reality reflection therapy for 30 min, 5x/wk for 4 wk. Outcomes were assessed at baseline and post-intervention.

**Outcomes**: Berg Balance Scale (BBS); Functional Reaching Test (FRT); Timed Up and GO (TUG); postural sway; 10 Metre Walk Test (10MWT).

1. The EG improved significantly compared to the CG on the BBS, FRT, TUG, postural sway (mediolateral sway distance with eyes open and eyes closed, anteroposterior and total sway distance with eyes open but not with eyes closed), and the 10MWT (p<0.05).

### 9.3.4 Feedback

#### Table 9.3.4.1 Summary of Studies Evaluating Feedback

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandel et al. (1990)</td>
<td>Canada</td>
<td>RCT</td>
<td>PEDro=3</td>
<td>TPS=NA</td>
<td>Single blind trial of 37 stroke patients randomized to 1 of 3 groups: No treatment control group; Received only EMG-BFB treatment group; Received EMG-BFB 1&lt;sup&gt;st&lt;/sup&gt; half of treatment and then rhythmic positional BFB for</td>
<td>Patients receiving rhythmic positional BFB significantly increased their walking speeds relative to other groups at post test and at follow-up.</td>
<td>Visual</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>Population</td>
<td>Intervention</td>
<td>Outcomes</td>
</tr>
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<tr>
<td>Chae et al. (2011)</td>
<td>South Korea</td>
<td>RCT</td>
<td>5</td>
<td>TPS=Chronic</td>
<td>N=21</td>
<td>24 standardized BFB sessions were performed over twelve weeks.</td>
<td>21 chronic stroke patients (&gt; 6 months) were randomized into a spinal stabilization exercise group and a conventional physiotherapy group. The spinal stabilization group performed 30 minutes of exercise 5x/week for 8 weeks. The exercises involved abdominal isometric contractions focusing on the transverse abdominis and multifidus muscles with visual biofeedback. Outcome measures included spatiotemporal gait parameters (velocity, cadence, step length, SLAR, SSAR, FAP) using the GAIT Rite apparatus. The results indicate significant differences in gait velocity, cadence, step length, and FAP score (functional ambulation profile) with p-values &lt;0.05. No significant change was observed in the control group.</td>
</tr>
<tr>
<td>Khallaf et al. (2014)</td>
<td>Saudi Arabia</td>
<td>RCT</td>
<td>5</td>
<td>TPS=</td>
<td>N=21</td>
<td>Population: Experimental group (EG; N=9): Mean age=51.1±9.2yr; Gender: Males=5, Females=5. Control Group (CG; N=10): Mean age=49.0±9.2yr; Gender: Males=7, Females=2. Intervention: The EG received real-time feedback during core stabilization exercise and met 3 times per week for 30 minutes for a period of 6 weeks for 30 minutes over the same period. Additionally, they received conventional physical therapy for five sessions of 30 minutes per week, for a period of 6 weeks. The CG performed core stabilization exercise without real time feedback; conventional physical therapy was also offered to them. Outcomes: Spatiotemporal parameters for gait and balance included gait velocity, cadence, step length, stride length, swing phase time during physical performance using GAITRite, and the Timed Up-and-Go Test (TUG).</td>
<td></td>
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<tr>
<td>Druzbicki et al. (2015)</td>
<td>Poland</td>
<td>RCT</td>
<td>7</td>
<td>TPS=</td>
<td>N=25</td>
<td>Population: Experimental Group (EG; N=25): Mean age=59.8±11.7yr; Gender: Males=17, Females=32. Overground Visual Cue At 8wk and 12wk improvements were seen in walking speed, symmetry, BBS, and functional mobility compared to baseline; however, there</td>
<td></td>
</tr>
<tr>
<td>Hollands et al. (2015)</td>
<td>UK</td>
<td>RCT</td>
<td>7</td>
<td>TPS=</td>
<td>N=18</td>
<td>Population: Treadmill Visual Cue Training group (T-VCT; N=18): Mean age=59.0±18.0yr; Gender: Male=11, Female=7. Overground Visual Cue At 8wk and 12wk improvements were seen in walking speed, symmetry, BBS, and functional mobility compared to baseline; however, there</td>
<td></td>
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</tbody>
</table>
### Druzbicki et al. (2016)

**Population:** Experimental Group (EG; N=19): Mean age=56.1±12.2yr; Gender: Male=14, Female=5. Usual Care group (CG; N=19): Mean age=60.0±13.6yr; Gender: Male=8, Female=11. **Intervention:** Participants were randomized to receive either over-ground visual cue training (O-VCT), treadmill based visual cue training (T-VCT) or usual care. All participants received their respective interventions 2x/wk for 8wk. Outcomes were assessed at baseline, 8wk, and 12wk follow-up. **Outcomes:** Walking Speed; Gait Symmetry; Berg Balance Scale (BBS); and Functional Mobility.

There was no significant difference between groups.

### Druzbicki et al. (2016)

**Population:** Experimental Group (EG; N=15): Mean age=61.9±11.4yr; Gender: Males=9, Females=6. Control Group (CG; N=15): Mean age=59.8±11.7yr; Gender: Males=5, Females=5. **Intervention:** EG received treadmill exercise training with visual biofeedback (VB) whereas CG received only treadmill training. All participants also received physiotherapy. Intervention occurred over 10 30min/d sessions over 2wk. Outcomes were assessed at baseline, post-treatment and at 6mo follow-up. **Outcomes:** Non-paretic and paretic: step length (SL); stance phase (ST); swing phase (SW); range of motion (ROM: hip and knee); gait symmetry indicators (intra-limb ratio of swing to stance time (SW/ST), step length ratio (SLR), stance phase ratio (STR), swing phase ratio (SPR), ROM knee ratio, ROM hip ratio).

1. Paretic ST and SL and non-paretic ST were significantly improved in EG at post-treatment (p=0.0007; p=0.0054; 0.0007) and 6mo follow-up (p=0.028; p=0.0076; p=0.0356) compared to baseline.
2. Paretic SW and non-paretic/paretic ROM hip and knee were significantly improved in EG at post-treatment compared to baseline (p<0.05), but not 6mo (p>0.05).
3. There were no significant within group differences for CG on any outcome measure for both time points (p>0.05).
4. At post-treatment, ROM in paretic hip was improved in EG compared to CG (p=0.0212). No significant between group differences for other outcome measures at post-treatment or 6mo (p>0.05).
5. STR at post-treatment was the only outcome significantly improved for gait symmetry indicators in favour of CG compared to EG at post-treatment (p=0.0297). No other significant differences were found between EG and CG at post-treatment or 6mo (p>0.05).

There were no significant differences between the EG and CG on the COP, sway area, weight symmetry, or TUG.
| Aruin et al. (2003) | 16 subjects with a narrow base of support an average of 18 days following stroke were randomized to receive conventional gait training for 10 days (twice daily for 25 min) or to gait training with a feedback device that was attached to the inside of the subject’s knees with Velcro tape and provided auditory feedback when the distance between the 2 sensors fell below the set threshold. Changes in step width with treatment were assessed with step print technique before and after treatment. | The experimental group of subjects improved their step width with treatment from 0.09 +/- 0.003 m to 0.16 +/- 0.006 m while individuals assigned to the control group showed smaller improvement from 0.099 +/- 0.004 m to 0.13 +/- 0.003 m. While both groups demonstrated statistically significant improvement (p < 0.05), the level of recovery of step width seen in the experimental group was greater. |
| Schauer et al. (2003) | 23 stroke patients were randomly assigned to receive either 15 sessions of conventional gait therapy or to a test group receiving therapy sessions with musical motor feedback. | Gait velocity, stride length, gait symmetry, foot rollover path length, and gait cadence significantly improved in the test group compared to the control group. |
| Sungkarat et al. (2011) | 35 subjects all within 6 months of first stroke were randomly assigned to an experimental (n = 17) or control group (n = 18). All subjects participated in 15, 1-hr rehabilitation sessions over 3 weeks. They included 30 minutes of gait retraining per session. During gait retraining, the experimental group used an insole shoe wedge and sensors set-up (l-ShoWS) while the control group received a conventional programme. The l-ShoWS set-up consisted of a wedge insole and a footswitch for the non-paretic leg and a pressure sensor on the paretic leg. Outcomes were assessed before and after treatment. They included gait speed, step length and single support time asymmetry ratio, balance and amount of load on paretic leg during stance were evaluated twice: one day before and after training. | Subjects in the experimental group demonstrated significantly greater improvement on the following outcomes compared with patients increase in standing and gait symmetry compared with those in the control group. Gait speed: 35.1 vs. 26.3 cm/s, p=0.02, step length asymmetry ratio: 0.37 vs. 0.78, p=0.03, single support time asymmetry ratio: 0.39 vs. 0.51, p=0.01, Berg Balance Scale: 45.6 vs. 41.8, p=0.06. |
| Chung et al. (2014) | Population: Experimental Group (EG; N=5): Mean age=66.2±5.0yr. Gender: Males=2, Females=3. Control Group (CG; N=7): Mean age=60.8±5.4yr. Gender: Males=2, Females=5. Intervention: The EG received usual gait training plus kinematic feedback. The individuals in this group were chronic stroke patients (1-year post stroke). The CG (Parkinson’s Disease, PD) received usual gait training. Outcomes: Mobility (gait speed, step length, endurance, quality); Gait quality (Tinetti Quality Inventory), Berg Balance Scale (BBS); Range of motion and strength. | 1. Participants from both groups demonstrated statistically significant within-group improvements in mobility measures (gait speed, step length, endurance, dynamic gait index) gait quality, balance, strength, and range of motion (affected and unaffected). For these outcomes, there were moderate to large effect sizes that ranged from 0.37 to 2.0 with a mean of 0.81. 2. Post exercise gain scores were of a larger effect size for the EG compared to the CG for gait quality (0.83), the Dynamic gait index (0.53), FTSTS (-0.31), the BBS (0.42) and flexibility on the unaffected side (0.46). * These effect sizes were of moderate to large magnitude. |
Both groups did not make significant improvements on the time balance tests (FTST and TUG), and the EG did not significantly improve in ROM on the most affected side.

3. Both groups did not make significant improvements on the time balance tests (FTST and TUG), and the EG did not significantly improve in ROM on the most affected side.

4. There were no statistically significant between group differences in gain scores for any of the outcome variables. Additionally, the effect sizes for these outcomes were small, and the mean effect size of these measures together was 0.27.

Jung et al. (2015)
South Korea
RCT
PEDro=7
TPSAsc=6.2mo
TPSSD=7.0mo
NStart=22
NEnd=21

Population: Augmented feedback Group (AF; N=78): Mean age=61.8±15.7yr; Gender: Males=47, Females=31. Feedback-only Group (SF; N=73): Mean age=65±13.2yr; Gender: Males=45, Females=28.

Intervention: Participants were randomized to a speed-only feedback (SF) group or to an augmented feedback (AF) group, generated by wireless sensors applied to the participant’s ankles during inpatient conventional therapy.

Outcomes: Average daily time spent walking; Functional ambulation category (FAC); 3-minute walking distance (3MWD); Stroke impact scale (SIS); 15 meters walk speed (15MWS).

1. No significant difference between the groups in the average daily time spent walking over the duration of the trial was found.

2. No significant difference in the 15MWS was found between the groups.

3. The FAC, SIS, and 3MWD scores were not significantly different between the groups at the end of the trial.

Ki et al. (2015)
Korea
RCT
PEDro=3
TPS=NA
NStart=30
NEnd=25


Intervention: The EG underwent 4 weeks of gait training and neurodevelopmental treatment, and additionally received auditory feedback during gait training. The CG received the same gait training as the EG, without the additional auditory feedback.

Outcomes: Stance phase and single limb stance phase of the paretic lower limb during gait; Timed Up-and-Go (TUG) test.

1. The EG exhibited an increase in the duration of the stance phase from 64.6% prior to training to 72.2% after the training. They also exhibited an increase in the duration of the single limb stance phase from 24.5% prior to training to 29.1% after training (p<0.01).

2. There were statistically significant within-group differences for the TUG test scores in the EG (p<0.01).

Yang et al. (2016)
Korea
RCT
PEDro=6
TPSAsc=11.18±3.68mo
TPSSD=11.97±3.53mo
NStart=24
NEnd=22

Population: Experimental Group (EG; N=11): Mean age=51.91±13.30yr; Gender: Males=9, Females=2. Control Group (CG; N=11): Mean age=55.82±13.58yr; Gender: Males=9, Females=2.

Intervention: EG received real-time auditory stimulation feedback during treadmill training whereas CG underwent treadmill training alone. Training occurred for 30min/d, 3d/wk for 4wk. All participants also received physiotherapy for 30min over 10 sessions/wk for 4wk. Outcomes were assessed at baseline and post-treatment.

Outcomes: Total perturbation distance; average perturbation velocity; TUG.

1. Total perturbation distance improved significantly in EG compared to CG when eyes were open and closed from baseline to post-treatment (p<0.05).

2. Average perturbation velocity improved significantly in EG compared to CG from baseline to post-treatment only when eyes were open (p<0.05).

3. TUG improved significantly in EG compared to CG at post-treatment (p<0.05).

4. All spatio-temporal measures (gait speed, cadence, step and stride length, limb support, gait asymmetry) were significantly improved.
<table>
<thead>
<tr>
<th>Therapist</th>
<th>Perturbation velocity; Timed Up and Go test (TUG); gait speed; cadence; step length paretic; stride length paretic; single limb support paretic; gait asymmetry.</th>
<th>in EG compared to CG from baseline to post-treatment (p&lt;0.05).</th>
<th>5. All outcomes were significantly improved from baseline to post-treatment in EG (p&lt;0.05), but not CG (p&gt;0.05).</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dobkin et al. (2010)</strong></td>
<td>179 stroke rehab inpatients were randomized to 2 groups to receive either feedback about self-selected fast walking speed (daily reinforcement of speed, DRS) immediately after a single, daily 10-m walk or no reinforcement of speed (NRS) after the walk, performed within the context of routine physical therapy. The primary outcome was velocity for a 15.2-m (50-foot) timed walk at discharge. Secondary outcomes were walking distance in 3 minutes, length of stay (LOS), and level of independence (Functional Ambulation Classification, FAC).</td>
<td>The walking speed at discharge for patients assigned to the DRS group (0.91 m/s) was greater (P = .01) than that for NRS (0.72 m/s). No difference was found for LOS. LOS for both DRS and NRS was significantly shorter, however, for those who had mean walking speeds &gt;0.4 m/s at entry. There were no significant differences between groups in the proportion of independent walkers (FAC ≥4) or distance walked in 3 min.</td>
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<tr>
<td><strong>Dorsch et al. (2015)</strong></td>
<td>Population: Group 1 (G1; N=8): Mean age=40.3±2.6 yr; Gender: Males=6, Females=2. Group 2 (G2; N=8): Mean age=41.2±3.1 yr; Gender: Males=6, Females=2. Intervention: Participants were randomly allocated to one of two groups: The study group (G1) received intensive mobility training and also a walking program with feedback from pedography, while the CG (G2) received a program of strengthening muscles and gait training with a solid ankle foot orthosis (AFO). The G1 group participated in the therapy for 90 minutes, 5 times a week, for 8 weeks, while the G2 group participated in 50-minute sessions, also delivered 5 times per week for 8 weeks. Assessments were conducted at baseline, after treatment, and at one-month follow-up. Outcomes: Foot placement: contact time and maximum force in different foot areas.</td>
<td>1. G1 showed a significant improvement regarding the time of contact and the maximum force for the hindfoot and all metatarsal heads (all p=0.001) [mean values provided in tables, no change in values provided]. 2. The maximum force values and the time of contact at post-training and at follow-up between the two groups differed significantly regarding all the foot areas (all p&lt;0.05).</td>
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<tr>
<td><strong>Mansfield et al. (2015)</strong></td>
<td>Population: Experimental Group (EG; N=29): Median age=64.0(22-92) yr; Gender: Males=20, Females=9. Control Group (CG; N=28): Median age=61.5(24-81) yr; Gender: Males=16, Females=12. Intervention: EG received an individualized walking program where accelerometer-feedback was provided to the physiotherapist. Feedback was not given to physiotherapist in CG. The intervention lasted the length of inpatient rehabilitation (~13d). Outcomes were assessed at baseline and the last 3d, which were averaged (post-treatment). Outcomes: total walking duration; total number of steps; average cadence per walk; longest walking distance.</td>
<td>1. Walking time, number of steps, number of long walks, and longest walk duration were not significantly different between EG and CG from baseline to post-treatment (p=0.74; p=0.39; p=0.21; p=0.56). 2. Average cadence was significantly improved following treatment in EG compared to CG (p=0.013). 3. EG spent less time in slow walking and more time in medium/brisk walking from baseline to discharge compared to CG (no p-value).</td>
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</tbody>
</table>
9. Mobility and the Lower Extremity

**Table 9.3.5.1 Summary of Studies Evaluating EMG Biofeedback**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Burnside et al.</strong> (1982)</td>
<td>UK</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=22</td>
<td>22 chronic stroke patients were randomized to receive a 6-week exercise program plus EMG-biofeedback (n=11) or an exercise program with sham EMG (n=11). Sessions were conducted twice weekly. Muscle strength rating of the tibialis anterior was made using the Medical Research Council (MRC) scale. Other assessments included active range of movement at the ankle and Basmajian’s rating scale for gait evaluation and were conducted at the end of treatment and at 12 weeks follow-up.</td>
<td>A significantly greater proportion of patients in the active EMG group demonstrated increased strength of dorsiflexion at the end of treatment and follow-up. Patients in both groups demonstrated improved range of motion at the end of treatment, although only the patients in the active EMG group maintained their gains at follow-up.</td>
</tr>
<tr>
<td><strong>Mulder et al.</strong> (1986)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS=NA</td>
<td>N=12</td>
<td>A RCT involving 12 stroke patients was performed with the purpose of comparing the effects of EMG feedback in the re-learning of motor control to the effects of a conventional physical therapy procedure (NDT). The therapy was focused on the improvement of the dorsiflexion function of the foot. Special attention was given to the measurement and evaluation of functional parameters (range of motion and gait).</td>
<td>The results indicated no significant differences between the 2 methods.</td>
</tr>
<tr>
<td><strong>Cozean et al.</strong> (1988)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=NA</td>
<td>N=36</td>
<td>Single blind RCT of 36 patients and 4 therapy groups: Control therapy consisting of standard physical therapy regimen; Electromyography Biofeedback (BFB); Functional electrically stimulation (FES); and Combined therapy with BFB and FES. 30 minutes of treatment three</td>
<td>Combined therapy of BFB and FES showed greater improvement indexes of knee flexion and ankle dorsiflexion compared to control, and either BFB or FES alone. Greatest gains in stride length and gait cycle time seen in the combined therapy group.</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Type</td>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Summary</td>
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<tr>
<td>Bradley et al. (1998)</td>
<td>UK</td>
<td>RCT</td>
<td>4</td>
<td>Acute</td>
<td>21</td>
<td>21 stroke patients randomized to receive either electromyography (EMG) biofeedback training in conjunction with physiotherapy or to receive physiotherapy alone (control). Significant improvement in active movement for all patients over time.</td>
<td></td>
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<tr>
<td>Intiso et al. (1994)</td>
<td>Italy</td>
<td>RCT</td>
<td>6</td>
<td>EG</td>
<td>11.3±12.6mo</td>
<td>Single blind trial of 16 stroke patients randomized to receive 1 of 3 treatments. Patients received either electromyography biofeedback therapy alone or standard physical therapy alone. Electromyography biofeedback (EMG BFB) was administered together with physical therapy; not including standard exercises of dorsiflexion of the foot. Physical therapy was administered according to the Bobath method including standard exercises for dorsiflexion of the foot. No significant differences in scores were noted on any of the outcome measures for the 2 groups.</td>
<td></td>
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<tr>
<td>Jonsdottir et al. (2010)</td>
<td>Italy</td>
<td>RCT</td>
<td>7</td>
<td>Chronic</td>
<td>20</td>
<td>20 subjects with chronic hemiparesis who were able to walk at least 10 m without an aid were randomized to receive conventional therapy that included task-specific training (20 sessions, each lasting 45 min, 3 times per week) or to conventional therapy plus EMG biofeedback. Quantitative gait analysis was performed before and after treatment and at follow-up (6 weeks). The EMG-biofeedback involved the triceps surae during functional gait activities. Treatment was administered with a fading frequency of biofeedback application and an increasing variability in gait activities. Patients in the biofeedback group achieved significant increases from baseline until the end of treatment (P&lt;.01) in peak ankle power at push-off (0.63 W/kg to 1.04 W/kg), gait velocity (28.3 %h/s to 39.6 %h/s) and stride length (44.5 %h to 57.6 %h). Increases remained significant at FU. There were no changes in any gait variable in the control group.</td>
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<tr>
<td>Lee et al. (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>EG</td>
<td>11.5±2.1mo</td>
<td>Population: Experimental Group (EG; N=15): Mean age=68.4±2.1yr; Gender: Males=8, Females=7. Control Group (CG; N=15): Mean age=67.0±3.20yr; Gender: Males=8, Females=7. Intervention: Participants were randomly assigned either to EG and performed mechanical horseback riding for 30mins daily, 5X/week for 6 weeks. The CG used horseback riding equipment and held onto handles to maintain posture. All participants also received Neurodevelopmental treatment for 30mins daily, 5X/wk, for total of 6 wks. Assessments were conducted before and after the intervention. Outcomes: Berg Balance Scale (BBS); Timed Up-and-Go Test (TUG); Beck Depression Inventory (BDI). 1. There were statistically significant improvements found in the BBS, TUGT, and BDI in the EG but not in the CG (p&lt;0.05). 2. Statistically significant between group differences were found for all measures (p&lt;0.05).</td>
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<tr>
<td>Xu et al. (2015)</td>
<td>China</td>
<td>RCT</td>
<td></td>
<td></td>
<td></td>
<td>Population: Experimental Group (EG; N=20): Mean age=58.8±11.0yr; Gender: Males=13, Females=7. Control Group (CG; N=20): Mean There was a significant difference at post-intervention between the two groups favoring the EG for the FMA (p&lt;0.05), and the FAC (p&lt;0.05).</td>
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</table>
9.3.6 Rhythmic Auditory Stimulation

Table 9.3.6.1 Summary of Studies Evaluating Rhythmic Auditory Stimulation

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Thaut et al.</strong> (1997)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=3</td>
<td>TPS&lt;3mo</td>
<td>N=20</td>
<td>20 patients were randomized to receive either twice-daily gait training with the addition of rhythmic auditory stimulation (RAS) or to receive twice-daily gait training. All patients trained twice daily for 30 min each am and p.m., 5 days a week for 6 weeks.</td>
</tr>
<tr>
<td><strong>Jeong et al.</strong> (2007)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&gt;6mo</td>
<td>N=36</td>
<td>36 community-dwelling subjects having sustained a stroke at least 6 months earlier were randomized to a regimen of either usual care (n=18) or an 8-week program of RAS-muscle movement program. Ankle flexion/extension on the affected side was measured using a goniometer before and after treatment.</td>
</tr>
<tr>
<td><strong>Thaut et al.</strong> (2007)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&lt;EG Mean=21.3d</td>
<td>TPS&gt;EG Mean=22.3d</td>
<td>N=78</td>
</tr>
<tr>
<td><strong>Kim &amp; Oh</strong> (2012)</td>
<td>Republic of Korea</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS=Chronic</td>
<td>N=a</td>
<td>This study looked at the effects of auditory stimulation during home-based rehabilitation on gait (walking speed) performance of chronic stroke patients. Twenty hemiparetic stroke patients were divided into an RAS group and a control group. The RAS group received RAS during gait training, while the control group received conventional therapy. The study showed statistically significant improvements in gait speed and symmetry between the groups.</td>
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</table>
randomized to an experimental or control group. All patients were instructed to practice/perform overground walking for 10min, 3 times a week, for 6 weeks at their home. Patients in the control group walked comfortably at their own speed, while patient’s in the experimental group walked while listening to a metronome beat (20 pulses per min, and increased by 20 pulses per minute every 2 min). Gait parameters (affected stride length, non-affected stride length, affected single support time, non-affected single support, and gait velocity) were measured pre-and post-intervention using the Rs scan system.

Cha et al. (2014) Korea RCT PEDro=7 TPSRAS=14.5mo TPSCG=14.7mo NStart=20 NEnd=20

**Population:** Rhythmic stimulation (RAS; N=10): Mean age=59.8±11.7yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=63.0±14.1yr; Gender: Males=6, Females=4.

**Intervention:** Participants were randomly assigned to the EG and received rhythmic auditory stimulation (RAS) training with intensive gait training, or to the CG and received intensive gait training without RAS. The therapy lasted 30 minutes per session, for 5 sessions per week, for a period of 6 weeks. In addition to the intervention, all patients received standard physical therapy. Participants were assessed the day before the start of the training and the day after the end of the training.

**Outcomes:** Berg balance scale (BBS); Stroke specific quality of Life scale (SS-QOL); gait parameters (velocity, stride length on the affected side, cadence, and double support period).

1. Both groups showed significant increases from pre-to post training in gait velocity, cadence and stride length (all p<0.05). The double support period showed improvements in the RAS group only (p<0.05).
2. The improvement in the RAS group was significantly greater than in the CG regarding gait velocity (p=0.024), cadence (p=0.040), and the stride length of the affected side (p=0.018).
3. The double support period was significantly more improved in the RAS group compared to the CG (p=0.005).
4. The BBS and SS-QOL scores showed significant improvements from pre-to post training in the RAS group (p<0.05), which were not observed in the CG. The difference in improvement was significantly different in the RAS group compared to the CG regarding the BBS (p<0.001) and the SS-QOL (p=0.000).

Suh et al. (2014) Korea RCT PEDro=6 TPSRAS=386.38d TPSCG=224.25d NStart=16 NEnd=16

**Population:** Rhythmic auditory stimulation Group (RAS; N=8): Mean age=61.00±14.48ys; Gender: Males=3, Females=5. Control Group (CG; N=8): Mean age=70.63±12.42yr; Gender: Males=3, Females=5.

**Intervention:** Participants were randomly assigned to either the intervention group and received rhythmic auditory stimulation (RAS) with gait training (for 15 minutes each session, 5 times a week with his/her guardian), or to the CG and received gait training (with 15 minutes, 5 times a week with his/her guardian) without RAS. Both groups received neurodevelopmental

1. There was no significant difference in cadence, gait velocity, and stride length between the RAS and the CGs after training.
2. The overall stability index and the mediolateral index of the standing balance parameter were found to be significantly different between the EG and the CG after training (overall stability index: ΔM_{RAS}=0.79, ΔM_{Con}=1.38, p=0.040; mediolateral index: ΔM_{RAS}=0.39, ΔM_{Con}=0.75, p=0.007).
3. Significant improvements from pretreatment to posttreatment in gait velocity (p=0.012), stride length (p=0.03), and cadence (p=0.012) were found in the EG and not observed in the CG.
therapy (NDT) for 30 minute each day, 5 times a week, for 3 weeks. Participants were assessed before the treatment (pre-) and after the completion of the treatment period (post-).

**Outcomes:** Cadence; gait velocity; stride length; overall stability index; anteroposterior index; mediolateral index.

4. The RAS group had much higher improvements in the overall stability index ($p=0.043$), mediolateral index ($p=0.016$), and anteroposterior index ($p=0.006$) compared to the CG.

5. Significant improvements from pre-treatment to post-treatment in the overall index ($p=0.011$), anteroposterior index ($p=0.011$), and mediolateral index ($p=0.014$) were found in the RAS group, but not in the CG.

### Park et al. (2015)
**Korea**
**RCT**
PEDro=5
**TPS** EG: 10.3±3.3mo
**TPS** CG: 12.5±4.2mo
**N start**=19
**N end**=19

**Population:** Experimental Group (EG; N=9): Mean age=51.8±12.5yr; Gender: Males=4, Females=5. Control Group (CG; N=10): Mean age=55.0±9.8yr; Gender: Males=6, Females=4.

**Intervention:** The EG received treadmill training paired with rhythmic auditory stimulation (RAS), and the CG received over ground walking with RAS. Training was 30min 5x/wk for 4wk. Outcomes were measured at baseline and post intervention.

**Outcomes:** Walking speed; step cycle; step length; Timed Up and Go test (TUG); 6 Metre Walk Test (6MWT); Functional Gait Assessment (FGA).

1. There was no significant difference between the two groups on the TUG.
2. EG improved significantly compared to CG in walking speed, step cycle, step length, 6MWT, and FGA ($p<0.05$).

### Song & Ryu (2016)
**Korea**
**RCT**
PEDro=5
**TPS** EG: 12.3±3.4mo
**TPS** CG: 14.75±6.0mo
**N start**=40
**N end**=40

**Population:** Experimental Group (EG; N=20): Mean age=57.0±7.8yr; Gender: Males=12, Females=8. Control Group (CG; N=20): Mean age=60.10±6.8yr; Gender: Males=9, Females=11.

**Intervention:** The EG received rhythmic auditory stimulation with treadmill training, while the CG received only treadmill training. Training was 30min 5x/k for 4wk. Outcomes were evaluated at baseline and post intervention.

**Outcomes:** Cadence; step length; Dynamic Gait Index (DGI); 10 Metre Walk Test (10MWT).

1. Both EG and CG experienced significant improvements in DGI scores, cadence, step length, 10MWT ($p<0.05$).
2. EG improved significantly more than the CG in cadence, step length, 10MWT, and DGI ($p<0.05$).

### Yoon & Kang (2016)
**Korea**
**RCT**
PEDro=4
**TPS** G1: 16.4±10.3yr
**TPS** G2: 13.6±8.5yr
**TPS** G3: 17.1±8.4yr
**N start**=30
**N end**=28

**Population:** Group 1 (G1; N=10): Mean age=50.8±14.4yr; Gender: Males=6, Females=4. Group 2 (G2; N=9): Mean age=56.3±7.1yr; Gender: Males=6, Females=3. Group 3 (G3; N=9): Mean age=61.2±13.0yr; Gender: Males=5, Females=4.

**Intervention:** Patients were randomized to receive treadmill training (G3), incline treadmill training (G2), or incline treadmill training with rhythmic auditory stimulation (G3). Training was 30min/d, 5d/wk for 4wk. Outcomes were assessed before and after.

1. All groups significantly improved on all outcome measures after training.
2. G1 showed significantly greater improvement on all outcome measures compared to G2 and G3 ($p<0.05$)
3. G2 showed significantly greater improvements on BBS, TUGT, 6MWT, SI, and speed compared to G3 ($p<0.05$).
9.3.7 Dual Task Training

Table 9.3.7.1 Summary of Studies Evaluating Dual Task Training

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td><strong>Yang et al. (2007)</strong> Taiwan RCT PEDro=7 TPS=Chronic N=25</td>
<td>25 chronic stroke subjects who were at least limited community ambulatory subjects (a minimum gait velocity, 58 cm/s) were randomized into a control group (n=12) or experimental group (n=13). Subjects in the control group did not receive any rehabilitation training. Subjects in the experimental group underwent a 4-week ball exercise program (30 min, 3x/wk). Gait performance was measured before and after treatment under single task (preferred walking) and tray-carrying task. Gait parameters of interest were walking speed, cadence, stride time, stride length, and temporal symmetry index.</td>
<td>There were significant between group differences favouring the experimental group for all selected gait variables except for temporal symmetry index under both task conditions.</td>
</tr>
<tr>
<td><strong>Shim et al. (2012)</strong> Republic of Korea RCT PEDro=5 TPS=Chronic N=35</td>
<td>Thirty-five hemiparetic chronic stroke patients were randomized to receive dual motor task training plus PT (experimental) or PT alone (control). PT was completed for 30min, 5 days a week for 6 weeks. For participants in the experimental group, dual motor training was performed following PT for 30min, 3 days a week for 6 weeks. The dual motor task involved walking while kicking a Styrofoam ball (suspended with string from a stick which the therapist held) with the knee on the non-paretic side followed by walking while kicking the ball with the foot of the paretic side. Gait abilities (speed, cadence, step length, stride length, single and double support period) were assessed pre- and post-intervention.</td>
<td>For patients in both groups, gait speed and cadence, step length, stride length, and single limb support period for both paretic and non-paretic legs significantly increased following the intervention (P&lt;0.05). Paretic and non-paretic double limb support periods significantly decreased in both groups (P&lt;0.05). Overall, change values post-intervention for gait speed and cadence, paretic single limb support periods, and paretic and non-paretic step and stride length were significantly different between groups (P&lt;0.05-0.001), in favour of the experimental condition.</td>
</tr>
<tr>
<td><strong>Cho et al. (2015)</strong> Korea RCT PEDro=7 TPSeg=273.9±191.74d TPScg=263.9±144.64d</td>
<td><strong>Population:</strong> Experimental Group (EG; N=11): Mean age=60.0±9.38yr; Gender: Males=5, Females=6. Control Group (CG; N=11): Mean age=58.6±11.86yr; Gender: Males=2, Females=3. <strong>Intervention:</strong> The EG received virtual reality training.</td>
<td>1. There were significant group by time interactions for gait speed (p=0.025), cadence (p=0.000), step length (p=0.000), and stride length (p=0.000) for the dual task condition favouring the EG over the CG. 2. In the single task condition, the EG did</td>
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</table>
treadmill training with cognitive load and the CG received virtual reality treadmill training alone. Training was 30min/d, 5x/wk for 4wk. Outcomes were assessed at baseline and post-intervention for both single and dual task conditions.

**Outcomes**: Gait speed; cadence step length; stride length.

significantly better than the CG on gait speed, cadence, step length and stride length (p<0.05).

**Population**: Experimental Group (EG; N=10): Mean age=64.8±10.5yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=54.6±11.8yr; Gender: Males=6, Females=4.

**Intervention**: The EG preformed dual-task training, and the CG used a balance board for balance training. Training was 30min, 5x/wk for 4wk. All participants also received conventional training for the same amount of time as the intervention. Outcomes were measured at baseline and after the intervention.

**Outcomes**: Berg Balance Scale (BBS); Mini-Mental State Examination (MMSE); Fugl-Meyer Assessment (FMA); Korean-Modified Barthel Index (KMBI).

No significant differences were observed between the EG and CG on the BBS, MMSE, FMA or K-MBI.

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**9.3.8 Mental Practice**

**Table 9.3.8.1 Summary of Studies Evaluating Mental Practice**

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Malouin et al. (2009) Canada RCT PEDro=6 TPS=Chronic N=12</td>
<td>12 chronic stroke subjects were randomly assigned to one of three groups: a group that combined with physical practice (MP), a group that combined physical practice with cognitive training (Cog) and a group without training (NOT). Training was provided three times per week for four weeks. Primary outcome was limb loading of the affected leg during rising/sitting. Outcomes were assessed at baseline, after training, and three weeks later.</td>
<td>The MP group demonstrated significantly greater increases in limb loading during both rising and sitting following treatment compared with the other 2 groups. (median= rising up: 18.4%; sitting down: 12.2%) compared with Cog group (median = rising up: -6.8%; sitting down: 5.4%) and a group without training (median= rising up: 6.2%; sitting down: 5.4%).</td>
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<tr>
<td>Braun et al. (2012) The Netherlands RCT PEDro=7 TPS=Subacute N=36</td>
<td>36 elderly stroke patients in 3 nursing homes were randomized to either: (1) experimental group receiving 6 weeks of multiprofessional rehabilitation, education on mental practice techniques and principles, and unguided mental practice outside of supervised therapy time. Standard tasks included “drinking” and</td>
<td>All patients improved from baseline on all lower extremity related outcomes. There were no significant differences between groups on self perceived performance of rehearsed activities or any other outcomes at either time point.</td>
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</table>
“walking” and patient selected tasks (1 arm and 1 leg) were practiced. The control group received the 6 weeks of rehabilitation and were also given “homework” to practice tasks that they had difficulty with. Unguided therapy in both groups was recorded in patient logs. Outcomes were assessed after the 6-week intervention period and at 6 months. Primary outcome assessed was self perceived performance (10-point NRS). Secondary outcome measures pertaining to the lower extremity were RMI, BBS and 10MWT. Barthel Index scores were also recorded.

**Schuster et al.** (2012) Switzerland  
RCT  
PEDro=7  
TPS>3mo  
N=41

41 stroke patients, >3 months following a first ever stroke, were randomized into one of three groups: mental imagery embedded into physiotherapy (experimental group 1; EG1), mental imagery added after physiotherapy (experimental group 2; EG2), or a control group (CG) that listened to audio tapes about stroke following physiotherapy. All patients received six physiotherapy sessions over the 2-week intervention. The motor task imaged was ‘Going down, lying on the floor, and getting up again’. The primary outcome measure was the time difference(s) in performing the motor task from pre-to post intervention.

All three groups significantly improved their performance (were faster) on the motor task after the two-week intervention. There were no performance differences found between the groups.

**Cho et al.** (2013) Korea  
RCT  
PEDro=6  
TPS=44.67±19.19mo  
TPS<0.05=45.54±16.71mo  
NStart=28  
NEnd=28

Population: Experimental Group (EG; N=15): Mean age=53.93±12.60yr; Gender: Males=9, Females=6. Control Group (CG; N=13): Mean age=53.85±12.44yr; Gender: Males=8, Females=5.

**Intervention:** The EG performed motor imagery training involving imagining normal gait movement for 15 minutes embedded in gait training for 30 mins (45 mins/day, 3 times/week). The CG performed gait training only (30 mins/day, 3 times/week).

**Outcomes:** Timed Up-and-Go Test, 10-m Walk Test and Fugl-Meyer assessment (FMA).

1. There were statistically significant improvements in the Timed Up-and-Go Test, and 10-m Walk Test in both groups.
2. For the Fugl-Meyer assessment, the EG demonstrated improvements, but the CG did not. This finding was statistically significant (p<0.05).
3. In regard to all other parameters, there were statistically significant differences between groups at follow-up (p<0.05).
4. Overall, the results of this study suggested that motor imagery training may be more effective than gait training alone in enhancing balance and gait abilities of chronic stroke patients.

**Kumar et al.** (2016) India  
RCT  
PEDro=7  
TPS<0.05=6.5±2.41mo  
TPS<0.05=5.6±2.20mo  
NStart=40  
NEnd=40

Population: Experimental Group (EG, N=20): Mean age=53.0±6.40yr; Gender: Males=16, Females=4. Control Group (CG; N=20): Mean age=51.0±5.80yr; Gender: Males=14, Females=6.

**Intervention:** The EG received task-oriented training and motor imagery, and the CG received only task training. Training was given to the lower extremity for 45-60min, 4x/wk.

1. There were a significant improvement in the EG compared to the CG hip flexors (p=0.01), hip extensors (p=0.01), knee extensors (p=0.01), knee plantarflexors (p=0.01), ankle dorsiflexors (p=0.01), and gait velocity (p=0.01).
2. There were no significant differences between the EG and CG knee flexors and ankle plantarflexors.
for 3 wk. The motor imagery training was an additional 30 min. Outcomes were assessed at baseline and post-intervention. **Outcomes:** Hip flexors; hip extensors; knee flexors; knee extensors; ankle dorsiflexors; ankle plantarflexors; gait velocity.

### 9.3.9 Mirror Therapy

#### Table 9.3.9.1 Summary of Studies Evaluating Mirror Therapy

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Traditional</strong></td>
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</tr>
<tr>
<td>Mohan et al. (2013)</td>
<td>India</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS&lt;sub&gt;EG&lt;/sub&gt;=7.09±3.18d</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=22</td>
<td>N&lt;sub&gt;End&lt;/sub&gt;=22</td>
</tr>
<tr>
<td>Ji &amp; Kim (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&lt;sub&gt;EG&lt;/sub&gt;=4.3±1.5mo, TPS&lt;sub&gt;CG&lt;/sub&gt;=4.5±1.3mo</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt;=34</td>
<td>N&lt;sub&gt;End&lt;/sub&gt;=31</td>
</tr>
<tr>
<td>Cha et al. (2015)</td>
<td>Korea</td>
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</tbody>
</table>

1. There were statistically significant within-group differences found for both groups with respect to FMA, BBA, and FAC scores.
2. Between-group comparisons of the change score from pre-to-post treatment for each of FMA, BBA were not statistically significant.
3. The only statistically significant finding was the change from pre-to-post treatment in FAC.
4. There were no significant differences observed between the groups in the change score for FMA.
5. Compared to the CG, the change score of FAC for the mirror group was greater, indicating a greater improvement. However, there were no statistically significant differences in the change score of the other outcome parameters.

**Stimulation**

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cha et al. (2015)</td>
<td>Korea</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1. The EG demonstrated significant improvements from pre-test to post-test on</td>
</tr>
</tbody>
</table>
9.3 Action Observation

Table 9.3.10.1 Summary of Studies Evaluating Action Observation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee et al.</td>
<td>Korea</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=36.79±26.07mo</td>
<td>Population: Experimental Group (EG, N=14); Mean age=55.71±6.70yr; Gender: Males=7, Females=7. Control Group (CG; N=13); Mean age=53.62±6.29yr; Gender: Males=7, Females=7.</td>
<td></td>
</tr>
<tr>
<td>Salhab et al.</td>
<td>Lebanon</td>
<td>RCT Crossover</td>
<td>PEDro=4</td>
<td>TPS=3-6mo</td>
<td>Population: Mean age=58.7±8yr, Gender: Male=10, Female=8,</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intervention: Participants with lower extremity impairment were randomized to receive conventional treatment (CG; N=9) or mirror therapy in combination with electrical stimulation (EG; N=9) for 2wk. Participants took a 1wk rest before receiving switching their type of therapy. Outcomes were assessed at baseline, post-treatment 1, post-treatment 2, and 1mo follow-up.</td>
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<td></td>
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<td></td>
<td></td>
<td>Outcomes: Range of Motion (ROM); Fugl-Meyer Assessment (FMA); 10 Meter Walk Test (10MWT).</td>
<td></td>
</tr>
</tbody>
</table>

EG group showed significantly greater improvements in ROM (p<0.0001), FMA (p<0.0001), and 10MWT (p=0.011) compared to the CG group; however, retention scores at 1mo were not significantly different from baseline (all p<0.05).
**Sample Size (N)**

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Start N</th>
<th>End N</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kim &amp; Kim</strong> (2012)</td>
<td>Republic of Korea</td>
<td>RCT</td>
<td>5</td>
<td>NA</td>
<td>30</td>
<td>This study examined the effect of action observation on walking performance for treatment of hemiparetic stroke. Thirty stroke patients were randomized to an experimental or control group. All patients received 30min of PT, however prior to each PT session patients in the experimental condition (action observation) watched 5 video clips (2min each) on proper walking performance from different viewpoints (anterior, posterior, and side views) and in different motions (fast vs. slow). Patients in the control group watched a 10min video in which they were taken through a stretching program. Spatiotemporal gait parameters (step length, single support time, double support time, velocity and cadence) were measured pre- and post-intervention via the GAITRite system.</td>
<td>Comparisons of the gait parameter measures following the intervention patient showed that the patient’s in the action observation group significantly improved on all spatiotemporal gait parameters in comparison to the control patient’s.</td>
</tr>
<tr>
<td><strong>Kim &amp; Lee</strong> (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>8.3mo</td>
<td>9</td>
<td>Population: Action observation training group (AOT; N=9): Mean age=55.3±12.1yr; Gender: Males=7, Females=2. Motor imagery training group (MIT; N=9): Mean age=54.8±8.8yr; Gender: Males=6, Females=3. Physical training group (PT; N=9): Mean age=59.8±8.9yr; Gender: Males=7, Females=2. Intervention: Participants were randomly allocated to one of three groups: (1) the action observation training (AOT) group which practiced additional action observation training, or (2) the motor imagery training (MIT) group which practiced additional motor imagery training, or (3) physical training (PT) group. The training was conducted over 5 sessions of 30 minutes each for 4 weeks. Assessments were conducted before and after the intervention. Outcomes: Timed Up-and-Go test (TUG); Functional Reaching Test (FRT); Walking Ability Questionnaire (WAQ); FAC; spatiotemporal gait parameters.</td>
<td>1. All groups improved on the TUG (AOT: MIT: p=0.003; PT: p=0.017), the FRT (AOT: p=0.002; MIT: p=0.000; PT: p=0.008), and on the WAQ (AOT: p=0.012; MIT: p=0.002; PT: p=0.017). 2. Only the AOT and the MIT groups improved significantly on the FAC (AOT: p=0.004; MIT: p=0.013). 3. A significant improvement was found in all groups on the gait speed (AOT: p=0.001; MIT: p=0.001; PT: p=0.021), cadence (AOT: p=0.002; MIT: p=0.002; PT: p=0.024), and on the step length of affected side (AOT: p=0.000; MIT: p=0.014; PT: p=0.014). 4. Only the AOT and MIT groups improved significantly on the stride length of affected side (AOT: p=0.000; MIT: p=0.019), single limb support of affected side (AOT: p=0.000; MIT: p=0.029), and the double limb support of affected side (AOT: p=0.008; MIT: p=0.008). 5. A significant difference in improvement between the groups was found on the TUG (p=0.045), cadence (p=0.002), and single limb support of affected side (p=0.018).</td>
</tr>
<tr>
<td><strong>Park et al.</strong> (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>4</td>
<td>14.8±61mo</td>
<td>40</td>
<td>Population: Experimental Group (EG; N=20): Mean age=51.15±14.81yr; Gender: Males=10, Females=10. Control Group (CG; N=20): Mean age=48.65±12.81yr; Gender: Males=11, Females=9. Intervention: Patients were randomized to receive gait training alone (CG) or with</td>
<td>1. Both groups showed significantly improvements on all outcome measures after treatment (p&lt;0.05). 2. EG showed significantly greater improvement than CG in 10MWT, TUGT, SS, and LOS after treatment (p&lt;0.05).</td>
</tr>
</tbody>
</table>
Gait training was delivered 20min/d, 5d/wk for 8wk. Action observation was delivered for 10min before each training session. Outcomes were assessed before and after treatment. **Outcomes:** 10-Metre Walk Test (10MWT); Timed Up & Go Test (TUGT); Limit of stability (LOS); Sway area (SA); Sway speed (SS).

### 9.3.11 Aquatic Therapy

#### Table 9.3.11.1 Summary of RCTs Evaluating Aquatic Therapy

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chu et al. (2004)</td>
<td>Canada</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=12</td>
<td>12 community-dwelling volunteers with stroke resulting in mild to moderate residual motor deficits were randomized to receive an aquatic exercise program for 1 hour, 3 times a week for 8 weeks or to an upper extremity intervention program (control). The experimental group exercised in chest-deep water at targeted heart rates located in a public community centre, while the control group performed arm and hand exercises while sitting. The main outcome measure was cardiovascular fitness ($\text{VO}_2$ max). Secondary measures included maximal workload, muscle strength, gait speed, and the Berg Balance Scale score.</td>
<td>The experimental group attained significant improvements over the control group in cardiovascular fitness, maximal workload, gait speed, and paretic lower-extremity muscle strength. The water-based exercise program resulted in a 22% improvement in cardiovascular fitness.</td>
</tr>
<tr>
<td>Furnari et al. (2014)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=NA</td>
<td>N=40</td>
<td>N=40</td>
<td><strong>Population:</strong> Experimental Group (EG; N=20): Mean age= 68±3yr; Gender: Males=10, Females=10. Control Group (CG; N=20): Mean age=72±5yr; Gender: Males=10, Females=10. <strong>Intervention:</strong> Hydrokinesytherapy. The EG was assigned an intensive aquatic therapy for 8 weeks in a waist-high pool offered in 1-hour sessions, 3 times per week, in addition to conventional physical therapy, also offered in 1-hour sessions, 3 times per week. The CG was assigned an 8-week physical therapy program, offered in 1-hour sessions, 6 times per week. Their program consisted of general conditioning exercises, including 10 mins of warming up, 20 mins of</td>
</tr>
</tbody>
</table>
lower and upper extremity strengthening, 20 mins of postural control exercise, including maintenance of standing and shifting the weight loads to the paretic side, 10 mins of gait training.

**Outcomes:** Plantar surface for each food (PS) (%); Plantar Load for each food (PL) (%); For the stabilometric analysis, Length of the ball (LLT) and index of energy expenditure required for maintaining orthostatic station with open and closed eyes. For the dynamic analysis, spatio-temporal gait parameters: Velocity (cm⁻¹); Cadence (steps min⁻¹); Semi-Step Length (StP) (%); Stance Phase (StP) (%); Swing Phase (SwP) (%); Double Support Phase (DsP) (%); Functional Independence Measure (FIM); Static Analysis (StA), Stabilometric Analysis (SA); Dynamic Analysis (DA).

4. Results from the stabilometric analysis (LLT with open eyes) revealed statistically significant within-group differences in EG and CG, as indicated by a reduction in scores.

5. Results from the Dynamic analysis showed that there were a number of statistically significant within-group differences for EG and CG.*

<table>
<thead>
<tr>
<th>Park et al. (2014)</th>
<th>Korea</th>
<th>RCT</th>
<th>PEDro=5</th>
<th>TPS=NA</th>
<th>N_start=22</th>
<th>N_end=22</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> Underwater treadmill group (UTG; N=10): Mean age=61.8±12.0yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=60.6±11.8yr; Gender: Males=5, Females=5. <strong>Intervention:</strong> The underwater treadmill gait program had a main exercise component for 30 minutes and the training program was performed twice a week for 4 weeks. The CG received a general rehabilitation program that was composed of motor exercise (ME), functional electrical stimulation (FES), and occupational therapy (OT). <strong>Outcomes:</strong> Postural stability test assesses anteroposterior, mediolateral, and total postural sway after the intervention.</td>
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<tr>
<td>1. There were statistically significant decreases in anteroposterior, mediolateral and total postural sway after the respective interventions for both groups (p&lt;0.05). 2. Both groups demonstrated statistically significant improvements in dynamic balance (p&lt;0.05).</td>
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<table>
<thead>
<tr>
<th>Matsumoto et al. (2016)</th>
<th>Japan</th>
<th>PCT</th>
<th>No Score</th>
<th>TPS_EG=22.8±14.4wk</th>
<th>TPS_CG=24.8±12.7wk</th>
<th>N_start=120</th>
<th>N_end=120</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> Experimental Group (EG, N=60): Mean age=62.4±10.7yr; Gender: Males=42, Females=18. Control Group (CG; N=60): Mean age=63.2±11.5yr; Gender: Males=39, Females=21. <strong>Intervention:</strong> All participants received conventional rehabilitation, but the EG also received underwater exercise. The underwater training was 30min, 2x/wk, for a total of 24 sessions. Outcomes were analyzed at baseline and 12wk. <strong>Outcomes:</strong> 10 Minute Walk Test (10MWT); Modified Ashworth Scale (MAS); Quality of Life (QOL).</td>
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<tr>
<td>The EG improved significantly compared to the CG on the 10MWT, MAS, and QOL (p&lt;0.01).</td>
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<table>
<thead>
<tr>
<th>Zhang et al. (2016)</th>
<th>China</th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> Experimental Group (EG, N=18): Mean age=54.7±7.59yr; Gender: Males=8,</td>
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<tr>
<td>The EG improved significantly compared to the CG on the FAC (p=0.009), BI (p=0.024),</td>
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</tbody>
</table>
RCT  
PEDro=8  
TPS<sub>EG</sub>=0.37±0.08yr  
TPS<sub>CG</sub>=0.34±0.07yr  
N<sub>Start</sub>=36  
N<sub>End</sub>=36

Females=10. Control Group (CG; N=18):  
Mean age=56.3±8.18yr; Gender: Males=9, Females=9.  
Intervention: The EG received aquatic therapy, and the CG received conventional therapy. Training was 40min, 5x/wk, for 8wk. Outcomes were assessed at baseline and post-intervention.  
Outcomes: Modified Ashworth Scale (MAS); Functional Ambulation Category (FAC); Barthel Index (BI); Knee kinematics (extension torque; flexion torque); Ankle kinematics (dorsiflexion torque; plantarflexion torque).

9.3.12 Horse Riding Simulation

Table 9.3.12 Summary of Studies Evaluating Hippotherapy

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Beinotti et al. (2010) | Brazil | PCT | No Score | TPS<sub>EG</sub>=60mo  
TPS<sub>CG</sub>=78mo  
N<sub>Start</sub>=20  
N<sub>End</sub>=20 | Population: Experimental Group (EG; N=10):  
Gender: Males=8, Females=2. Control Group (CG; N=10): Mean age=52yr; Gender: Males=6, Females=4.  
Intervention: The EG received conventional treatment and hippotherapy (horse therapy), while the CG only received the conventional treatment. The CG received conventional treatment 3x/wk for 16wk, totalling 48 sessions. The EG performed conventional therapy 2x/wk and horse therapy 1x/wk, for a total of 16wk; total of 48 sessions.  
Outcomes: Functional Ambulation Category Scale (FAS); Fugl-Meyer Assessment Scale (FMA); Berg Balance Scale (BBS); Cadence. | 1. There were statistically significant improvements in motor function in total and between groups (p=0.01) as shown by the FMA.  
2. In all subjects together, there was a statistically significant improvement in the BBS (p=0.007).  
3. There was no significant difference between groups with respect to average cadence (p=0.19).  
4. There was no significant improvement in either the EG or CG with respect to the FAS. |
| Han et al. (2012) | South Korea | PCT | No Score | TPS<sub>EG</sub>=11.6±3.2mo  
TPS<sub>CG</sub>=12.4±3.7mo  
N<sub>Start</sub>=37  
N<sub>End</sub>=37 | Population: Experimental Group (EG; N=19):  
Mean age=61.1±6.3yr; Gender: Males=13, Females=6. Control Group (CG; N=18): Mean age=62.2±6.9yr; Gender: Males=11, Females=7.  
Intervention: Mechanical horseback riding therapy system. Patients in the EG received 20 mins of mechanical horseback riding therapy 2x/wk for 12 wk, and also received conventional physiotherapy. The CG received only conventional therapy and it consisted of neurodevelopmental therapy. | 1. There was a statistically significant improvement in balance parameters in the EG and CG at 12 weeks, however, there was no significant difference between groups (p>0.05).  
2. There was no significant difference in gait parameters for either the EG or CG, and no significant difference between groups (p>0.05).  
3. There was a statistically significant improvement in the B-POMA assessment in the EG at 12 weeks after treatment (p=0.001,
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>RCT</th>
<th>PEDro</th>
<th>TPS</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sung et al. (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>TPS=19.2±16.5mo</td>
<td>N Start=20</td>
<td>N End=20</td>
<td>Experimental Group (EG; N=10): Mean age=48.2±8.2yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=54.2±10.4yr; Gender: Males=6, Females=4.</td>
<td>The EG received a hippotherapy simulator for 15 mins/day, 5 times/week for 4 weeks, in addition to conventional rehab for 45 mins/day. The CG received conventional rehabilitation for 60 min/day, 5 times /week for 4 weeks.</td>
<td>Functional Ambulation Category (FAC); Gait part of Performance Oriented Mobility Assessment (G-POMA); Balance Part of Performance Oriented Mobility Assessment (B-POMA).</td>
</tr>
<tr>
<td>Baek et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>3</td>
<td>TPS=NA</td>
<td>N Start=30</td>
<td>N End=30</td>
<td>Experimental Group (EG; N=15): Mean age=55.1±6.1yr; Gender: Males=7, Females=8. Control Group (CG; N=15): Mean age=56.5±7.5yr; Gender: Males=8, Females=7.</td>
<td>Horse riding simulation training that simulates three directional movements (anterior-posterior, lateral, upward-downward). The CG performed trunk exercises using Swiss balls for 8 weeks (3 sessions per week, and each session was 30 mins in length). *Both groups received central nervous system developmental therapy for 30 mins.</td>
<td>Balance ability, and the changes in abdominal muscle thickness: i) Three – directional movements were measured; ii) Static balance ability (centre of pressure [COP] path length and COP travel speed); iii) Changes in abdominal muscle thickness were measured three times, with an average taken after (transversus abdominis muscles).</td>
</tr>
</tbody>
</table>
9. Mobility and the Lower Extremity

Lee et al. (2014)
Korea
RCT
PEDro=4
TPS=NA
NStart=30
NEnd=30

Population: Hippotherapy therapy (N=15):
Mean age=63.8±6.2yr; Gender: Males= 11,
Females=4. Treadmill group (N=15): Mean
age=64.3±4.8yr; Gender: Males=12,
Females=3.

Intervention: The experimental group
received hippotherapy. The control group
received treadmill training. Each of these
training interventions was conducted in 30-
minute sessions administered 3 days per week,
for 8 weeks.

Outcomes: Berg Balance Scale score, gait
velocity and step length asymmetry ratio (%).

1. There were statistically significant
improvements in the hippotherapy training
group found for the BBS score, gait velocity,
and step length asymmetry ratio (p<0.05).
2. For the treadmill training group, the only
statistically significant improvements found
after training was in the step length
asymmetry ratio (p<0.05). There were no
other statistically significant differences in
outcomes after the treadmill training.
3. There were no statistically significant
differences in BBS scores between groups,
however, there were statistically significant
differences between groups for gait velocity
and step length asymmetry ratio (p<0.05).

Kim & Lee (2015)
South Korea
RCT
PEDro=4
TPS=23.6±2.8mo
NStart=20
NEnd=17

Population: Mean age=63.9±8.7yr; Gender:
Males=10, Females=7.

Intervention: Simulated horseback riding
therapy was performed for 30 mins, 5x/wk,
for 6wks.

Outcomes: Trunk impairment scale (TIS);
Functional Gait Assessment (FGA): gait
velocity,Cadence, stride length of the
affected and unaffected sides, and double
limb support of the affected and unaffected
sides.

1. There were statistically significant within-
group differences before and after training
(p<0.05).
2. With eyes open, and closed, the results
showed statistically significant differences in
sway area, distance, and velocity before and
after training (p<0.05 for all). *
3. There were statistically significant within-
group differences before and after training
with respect to all FGA components (p<0.05).

Lee & Kim (2015)
Korea
RCT
PEDro=6
TPSinc=11.5±2.1mo
TPSdec=12.1±3.1mo
NStart=30
NEnd=30

Population: Experimental Group (EG; N=15):
Mean age=68.4±2.1yr; Males=8, Females=7.
Control Group (CG; N=15): Mean
age=67.0±3.2yr; Gender: Males=8,
Females=7.

Intervention: Patients were randomized to
receive conventional rehabilitation alone
(CG) or with simulated horseback riding
(EG). Both were delivered 30min/d, 5d/wk
for 6wk. Outcomes were assessed ebfore
and after treatment.

Outcomes: Berg Balance Scale (BBS); Timed
Up & Go Test (TUGT).

1. EG showed significant improvements on BBS
and TUGT after treatment, while CG did not.
2. EG showed significantly greater
improvements on BBS and TUGT compared
to CG.

9.3.13 Self-Management Programs

Table 9.3.13.1 Summary of Studies Evaluating Self-Management Programs

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
</table>

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Lindvall & Forsberg (2014) Sweden RCT PEDro=7 TPSEG=4.1yr TPSCG=4.2yr NStart=46 NEnd=42

**Population:** Experimental group (EG; N=24): Mean age=62.1±11.4yr; Gender: Males=12, Females=12. Control group (CG; N=22): Mean age=65.6±9.2yr; Gender: Males=15, Females=7.

**Intervention:** Patients were randomly allocated either to the EG and participated in a body awareness therapy in groups once a week, or to the CG where no further intervention was introduced. The intervention period lasted 8 weeks. Assessment were conducted before the intervention period, after the intervention, and at 4-6-week follow-up.

**Outcomes:** Berg Balance Scale (BBS); Timed Up-And-Go Test (TUG); 6-minute walk test (6MWT); TUG+Cognitive test; Activities-specific Balance Confidence Scale (ABCS); Short Form-36 (SF-36); Timed-Stands tests.

1. The EGEG improved significantly at the end of the intervention period on the BBS (p<0.0001), TUG (p=0.0009), and the 6MWT (p=0.028). A significantly improvement in the EGEG was found at week 14 on the BBS (p<0.001), and the TUG (p=0.0092).
2. The CG improved significantly at 14 weeks on the TUG (p=0.0006), and on the Timed-Stands test (p=0.0024).
3. A significant difference between the two groups was found at 14 weeks on the BBS (p=0.029), and on the Timed-Stands tests (p=0.026).

Liu & Chan (2014) Hong Kong RCT PEDro=7 TPSEG=13.80d TPSCG=12.90d NStart=46 NEnd=42

**Population:** Experimental Group (EG; N=24): Mean age=69.70±6.00yr; Gender: Males=11, Females=13. Control Group (CG; N=20): Mean age=72.30±9.90yr; Gender: Males=11, Females=9.

**Intervention:** Patients were randomly assigned either to the self-regulation group (SR) for promoting motor and cognitive performance, or to the CG and received functional rehabilitation. The duration of the intervention was a week, with a prescription of 1 hr sessions daily. Assessments were conducted before and after the intervention.

**Outcomes:** Cognitive and motor performance: Functional Independence Measure (FIM); Fugl Meyer Assessment (FMA); CTT.

1. The CG improved significantly on the FIM (motor: p<0.001; cognitive: p=0.020) but not the FMA-LE.
2. The CG improved significantly on FMA-UE (p=0.002).
3. The SR group improved significantly on the FIM (motor: p<0.001; cognitive: p<0.001), CTT (subtest 1: p=0.002), and on the FMA-LE (p<0.001).
4. The SR group improved significantly on the FMA-UE (p<0.001).
5. A significant difference in improvement was found between the groups regarding the motor subscale of the FIM (p=0.002).

### 9.3.14 Caregiver-Mediated Programs

#### Table 9.3.14.1 Summary of Studies Evaluating Caregiver-Mediated Programs

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang et al. (2015)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPSSEG=18mo</td>
<td>TPSCG=18.5mo</td>
<td>NStart=51</td>
<td>NEnd=51</td>
</tr>
</tbody>
</table>

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intervention period lasted 12 weeks. Assessments were conducted at baseline and at the end of the intervention. **Outcomes**: Stroke Impact Scale (SIS); Berg Balance Scale (BBS); 10-meter Walk test (10MWT); 6-minute walk test (6MWT); Barthel Index (BI); Caregiver Burden Scale (CBS).

3. No significant difference between groups on the CBS was found.

**Van Den Berg et al.** (2016) The Netherlands RCT PEDro=8 TPS_{EG}=22.4±13.3d TPS_{CG}=13.9±7.9d N_{Start}=63 N_{End}=60

**Population**: Experimental Group (EG; N=31): Mean age=64.5±18.5yr; Gender: Males=19, Females=12. Control Group (CG; N=32): Mean age=70.1±12.4yr; Gender: Males=21, Females=11.

**Intervention**: The EG received caregiver-mediated exercise program with e-health support, and the CG received usual care. Training was performed for 30min, 5x/wk for 8wk. Outcomes were assessed at baseline (T0), 8wk (T1), and 12wk (T2).

**Outcomes**: Stroke Impact Scale (SIS); Timed Up and Go (TUG); length of stay; Nottingham Extended Activities of Daily Living (NEADL); General Self-Efficacy Scale (GSES).

1. Intention-to-treat analysis revealed that there were no significant difference between the EG and CG on the SIS mobility or length of stay at T1 or T2. There was a significant improvement in the EG compared to the CG on the SIS memory domain (p=0.0018) at T2. The CG performed significantly better than the EG on the strength domain of the SIS (p=0.0299) and the TUG (p=0.0307) at T2.

2. Per-protocol analysis revealed the EG had a significantly shorter length of stay than the CG, and the EG also did significantly better on the NEADL at 8wk (p=0.0118). There were no significant differences between the EG and CG on the SIS mobility scale and GSES.

### 9.4 Strength and Resistance Training

**Table 9.4.1 Summary of Studies Evaluating Strength and Resistance Training**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td><strong>Progressive Resistance Training</strong></td>
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</tr>
<tr>
<td>Moreland et al. <strong>(2003)</strong></td>
<td>Canada</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=6mo</td>
<td>N=133</td>
<td>133 stroke patients were randomized to the experimental group, receiving 9 lower-extremity progressive resistance exercises or to the control group who performed the same exercises without resistance. All patients received conventional physiotherapy.</td>
<td>No significant difference on the rate of change on the Disability Inventory or the 2-minute walking test was found between the groups.</td>
</tr>
<tr>
<td>Ouellette et al. <strong>(2004)</strong></td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=6-72mo</td>
<td>N=42</td>
<td>42 volunteers &gt; 50 years, 6 mos - 6 yrs. following mild to moderate stroke, were randomized into either a control group consisting of upper extremity stretching or a progressive resistance training (PRT) group that received a 12-week supervised high-intensity resistance training program consisting of bilateral leg press (LP), unilateral paretic and nonparetic knee extension (KE), ankle dorsiflexion (DF), and plantarflexion</td>
<td>Subjects in the PRT group had achieved significant improvements in LP, paretic KE and nonparetic KE compared with the control group who did not. Patients in the PRT group achieved significantly greater levels of improvement in paretic ankle DF, paretic ankle PF and nonparetic ankle PF. The PRT group showed significant improvement in self-reported function and disability with no change in the control. There was no significant difference</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>Subjects</td>
<td>Intervention</td>
<td>Measures</td>
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</tr>
<tr>
<td>Yang et al. (2006)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>7</td>
<td>TPS=Chronic</td>
<td>N=48</td>
<td>48 chronic, hemiparetic stroke patients not currently receiving any rehabilitation were randomly allocated to an experimental group that received 4 weeks of task-oriented progressive resistance strength training (n=24) or a control group that received no treatment (n=24). At the end of treatment, the following outcome measures were assessed: lower extremity muscle strength, cadence, stride length, timed up and go test, gait velocity, step test and the six-minute walk test.</td>
<td>Patients in the experimental group demonstrated significant improvements in all of the outcomes assessed with the exception of the step test. Patients in the control group who received no therapy improved in several areas (knee flexors, ankle dorsiflexion on the unaffected side, and the step test).</td>
</tr>
<tr>
<td>Mead et al. (2007)</td>
<td>UK</td>
<td>RCT</td>
<td>8</td>
<td>TPS=median=171 TPS=median=147.5</td>
<td>N=66</td>
<td>66 ambulatory patients stroke patients who had completed inpatient rehabilitation were randomized to receive a 12-week outpatient program of strength and resistance exercise (n=32) or relaxation (n=34). Treatments were provided for 1.5 hrs, 3 times per week. Outcomes were assessed at 3 and 7 months and included: FIM, Nottingham Extended Activities of Daily Living; Rivermead Mobility Index; functional reach; sit-to-stand; elderly mobility score; timed up-and-go; Medical Outcomes Study 36-Item Short Form Questionnaire, version 2 (SF-36); Hospital Anxiety and Depression Score; aspects of physical fitness (comfortable walking speed, walking economy, and explosive leg extensor power).</td>
<td>At 3 months, the role-physical component of the SF-36, timed up and go and walking economy were significantly better among patients in the exercise group compared with the relaxation group. By 7 months, the only difference that remained between groups was the role physical component of the SF-36.</td>
</tr>
<tr>
<td>Flansbjer et al. (2008)</td>
<td>Sweden</td>
<td>RCT</td>
<td>6</td>
<td>TPS=6-48mo</td>
<td>N=24</td>
<td>24 community-dwelling stroke subjects were randomized to either a training group (n = 15) and participated in supervised progressive resistance training of the knee muscles (80% of maximum) twice weekly for 10 weeks, or to a control group (n = 9) who continued their usual daily activities. Both groups were assessed before and after the intervention and at follow-up after 5 months. Muscle strength was evaluated dynamically and isokinetically (60 degrees /sec) and muscle tone by the Modified Ashworth Scale. Gait performance was evaluated by Timed &quot;Up &amp; Go&quot;, Fast Gait Speed and 6-Minute Walk tests, and perceived participation by Stroke Impact Scale.</td>
<td>Dynamic and isokinetic knee muscle strength increased in both groups over the treatment period, although the improvement was significantly greater in the training group. Similarly, both groups improved in gait performance, but at follow-up only Timed &quot;Up &amp; Go&quot; (TUG) and perceived participation were significantly better for the training group. At the 4 years follow up, improved muscle strength of the training group was maintained as were improvements in the TUG, 6MWT and fast gait speed. The control group, on the other hand showed deterioration in fast gait speed and 6 minute walk distance.</td>
</tr>
<tr>
<td>Lee et al. (2010)</td>
<td>Australia</td>
<td>RCT</td>
<td>8</td>
<td></td>
<td>48</td>
<td>48 individuals with stroke onset at least 3 months were randomly allocated to one of four treatment groups: progressive resistance training (PRT) + cycling, PRT + sham cycling,</td>
<td>Patients undergoing PRT improved their lower limb muscle strength, peak power and endurance compared with participants receiving sham PRT or cycling only (P&lt;0.05). Combined exercise was not</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>Start</td>
<td>End</td>
<td>Population</td>
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<td>-------</td>
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</tr>
<tr>
<td>Moore et al. (2016)</td>
<td>UK</td>
<td>RCT</td>
<td>5</td>
<td>19±26mo</td>
<td>40</td>
<td>40</td>
<td>Mean age=69±9yr, Gender: Males=34, Females=6.</td>
</tr>
<tr>
<td>Bale &amp; Strand (2008)</td>
<td>Norway</td>
<td>RCT</td>
<td>6</td>
<td>Subacute</td>
<td>18</td>
<td>18</td>
<td>18 subacute phase post-stroke patients were randomly allocated to a functional strength training group (n = 8) and a training-as-usual group (n = 10). The functional strength training group participated in functional progressive strength training of the affected lower extremity. The training-as-usual group had traditional training, excessive muscle power being avoided to prevent associated reactions. All trained 50 minutes five days a week for four weeks. Maximum weight-bearing in standing was the primary outcome was assessed before and after treatment. Isometric muscle strength, gait speed and items of Motor Assessment Scale</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Start</th>
<th>End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lee et al. (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td>19.2mo</td>
<td>28</td>
<td>28</td>
<td>Progressive Resistance Training group (PRT; N=14): Mean age=60.3±7.5yr; Gender: Males=9, Females=5. Control Group (CG; N=14): Mean age=61.1±8.6yr; Gender: Males=8, Females=6.</td>
<td>Participants were randomly allocated either to the EG and received progressive resistance training (PRT) for 30 minutes, 5 days per week for 6 weeks, or to the CG and maintained routine activities. Assessments were conducted at pre- and at post-intervention.</td>
<td>Outcomes: Gait: step length; stride length; Heel-to-heel of Support (H-H BOS); step time; double support; gait velocity.</td>
<td>1. The PRT group improved significantly regarding all outcome measures (all p&lt;0.05). 2. A significant difference in the post-intervention values between the two groups was found on all outcome measures (p&lt;0.05).</td>
</tr>
</tbody>
</table>

Functional Strength Training

1. Maximum weight-bearing on the affected leg improved more in the functional strength training group (mean 17.4% of body weight) than in the training-as-usual group (mean 5.6% of body weight), but taking test data at inclusion into consideration, the difference in change was not statistically significant (P = 0.056). More patients in the functional strength training group (57%) could weight-bear on the affected leg while stepping forward, than in the training-as-usual group (17%). Improvement was clinically significant in 7 of 9 outcome measures in the functional strength training group (effect size > or =
were also assessed.

**Cooke et al.** (2010)
UK
RCT
PEDro=7
TPS\text{mean}=34
N=109

109 stroke subjects, a mean of 34 days after stroke, with some voluntary muscle contraction in the lower limb were randomized to one of three groups that received treatment for 1 hr/day x 4 days/week x 6 weeks (24 hrs total). The 3 groups were, conventional physiotherapy (CPT) (n=35), CPT+CPT (n=35) and functional training (FST) + CPT (n=38). Outcomes were measured 6 weeks after baseline and at follow-up 12 weeks thereafter. The primary outcome was walking speed (m/s). Secondary outcomes included ability to walk >0.8m/s (i.e. community ambulation), knee extensor torque, and functional mobility.

1. There were no differences in gait speed at the end of treatment or at follow-up for the treatment contrast of CPT vs. FST+CPT (p=0.33 and p=0.666, respectively). There were no significant differences in any of the other outcomes (CPT vs. CPT+FST) at the end of treatment or follow-up.

**Mares et al.** (2014)
UK
RCT
PEDro=8
TPS\text{EG1}=24.4mo
TPS\text{EG2}=24.4mo
N\text{Start}=52
N\text{End}=44

Population: Experimental Group (EG1; N=27): Mean age=67.6±12.9yr; Gender: Males=18, Females=9. Experimental Group 2 (EG2; N=25): Mean age=69.0±13.7yr; Gender: Males=17, Females=8.

Intervention: Participants were randomly allocated either to Functional strength training (FST) for the upper limb group, or to the FST for the lower limb group. Assessments were conducted at baseline, after 6 weeks of the intervention, and at 6-week follow-up.

Outcomes: Action Reach Arm Test (ARAT); Functional Ambulation Categories (FAC); Modified Rivermead Mobility Index (MRMI); Timed Up-and-Go Test (TUG); 9-Hold Peg Test (9HPT).

1. A significant difference in the improvement on the ARAT was found between the two groups at the end of the intervention (p=0.042) and at follow-up (p=0.019).
2. A significant difference in improvement at the end of the intervention between the two groups regarding the TUG was found (p=0.047), however the effect was not maintained at follow-up. No other significant differences between groups was found on any of the remaining outcome measures.

**Glasser** (1986)
USA
RCT
PEDro=4
TPS=NA
N=20

20 patients were randomly assigned to either an experimental group or a control group. The control group received therapeutic exercise program and the experimental group received therapeutic exercise program plus isokinetic exercise. The Functional Ambulation Profile (FAP) was administered to the patients before and after the 5-week study period.

All patients showed improvement in the rate of ambulation and in overall ambulation performance. The difference in ambulation times and FAP scores between the groups was not significant.

**Kim et al.** (2001)
Canada
RCT
PEDro=7
TPS=Chronic
N=20

20 stroke patients were randomized to receive either maximal isokinetic strengthening or passive range of motion. Interventions were provided 3 times a week for 6 weeks.

There was no significant difference between groups on changes in walking speed. There was a non-significant trend toward greater strength improvement in the strength-training group compared to the passive range of motion group.
Lee & Kang (2013)  
Korea  
RCT  
PEDro=3  
TPS=NA  
N=20  

**Population:** Experimental Group (EG; N=10): Mean age=53.40±9.71yr; Gender: Males=7, Females=3. Control Group (CG; N=10): Mean age=53.86±10.56yr; Gender: Males=6, Females=4.  

**Intervention:** Patients were randomized to receive conventional rehabilitation alone (CG) or with isokinetic eccentric resistance training (EG). EG received additional training for 60min/d, 3d/wk for 6wk. Outcomes were assessed at baseline, 3wk, and 6wk.  

**Outcomes:** Gait velocity; Peak torque; Stairs Test (ST); Timed Up & Go Test (TUGT).  

1. CG did not improve on any outcome measure at 3wk or 6wk.  
2. EG significantly improved on all outcome measures at 6wk (p<0.05) but not at 3wk.  
3. EG showed significantly greater improvement than the CG on all outcome measures after 6wk (p<0.05).

Şen et al. (2015)  
Turkey  
RCT  
PEDro=5  
TPS=EG=3(2-8) mo  
TPS=CG=3(2-9) mo  
N_{Start}=50  
N_{End}=50  

**Population:** Experimental Group (EG, N=25): Mean age=51.3±12.0yr; Gender: Males=17, Females=8. Control Group (CG; N=25): Mean age=55.4±10.5yr; Gender: Males=16, Females=9. Healthy Subjects (HS, N=30): Mean age=49.9±8.8yr; Gender: unspecified.  

**Intervention:** All subjects received conventional rehabilitation and the EG also received isokinetic bilateral strength training for the lower limb. Training was 5x/wk for 3wk. There was also a healthy control group as well as a control group in which the participants had a previous stroke. Outcomes were assessed at baseline and post-intervention.  

**Outcomes:** Function Independence Measure (FIM); Stroke Specific Quality of Life scale (SS-QOL); 10 Metre Walk Test (10MWT); 6 Metre Walk Test (6MWT); Stair Climbing Test; Timed Up and Go test (TUG); Berg Balance Scale (BBS); Rivermead Mobility Index (RMI).  

1. The peak torque values of the knee improved significantly in the EG compared to the CG (p<0.025).  
2. There was a significant improvement in the EG compared to the CG on the SS-QOL, FIM, 10MWT, 6MWT, TUG, BBS, Stair-Climbing Test, and RMI (p<0.025).

Clark & Patten (2013)  
USA  
RCT  
PEDro=8  
TPS_{ECC}=12.8mo  
TPS_{CON}=13.3mo  
N_{Start}=35  
N_{End}=33  

**Population:** Eccentric resistance training (ECC; N=16): Mean age=59.7±10.9yr; Gender: Males=11, Females=5. Concentric resistance training (CON; N=18): Mean age=63.2±10.6yr; Gender: Males=14, Females=4.  

**Intervention:** Participants were randomly allocated to receive ECC, or to receive CON. The intervention lasted 5 weeks delivered 3 times weekly. Both groups performed additional gait training 3 days per week for 3 weeks after the intervention period. Assessments were conducted at baseline, following resistance training, and following gait training.  

**Outcomes:** Gait, muscle function: neuromuscular performance during leg extension; neuromuscular activation; muscle strength; torque; angular position; angular velocity; electromyographic recordings; walking  

1. The ECC group showed larger improvements in the neuromuscular activation of the paretic leg muscles (rectus femoris, and vastus medialis) (p<0.005), and the largest gain in paretic leg power (p<0.0001).  
2. ECC had greater cross-education of increased power to the untrained non-paretic leg (p=0.006).  
3. During gait training, the gain in the paretic leg activation in the ECC group was lost, and the net change in agonist activation was comparable between the two groups when the intervention was completed. Therefore, no difference between the two groups was found.  
4. The SS and FS walking speed improved significantly in both groups (SS; CON: p=0.002, ECC: p<0.0001. FS; CON: p=0.0006,
<table>
<thead>
<tr>
<th>Speed (self-selected (SS)); fastest comfortable (FS) walking speed.</th>
<th>ECC p&lt;0.0001). 5. No significant difference in the improvement on the SS or FS walking speed between the two groups was found.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fernandez-Gonzalo et al. (2016) Sweden RCT PEDro=5 TPS CG=3.5±3.6yr TPS EG=4.3±4.9yr NStart=32 NEnd=29</td>
<td>Population: Experimental Group [EG; N=14]: Mean age=61.2±9.8yr; Gender: Males=11, Females=3. Control Group [CG; N=15]: Mean age=65.7±12.7yr; Gender: Males=11, Females=4. Intervention: The EG performed emphasizing eccentric-overload flywheel resistance exercises with the more-affected lower limb. The CG just continued to follow their daily routine. Training was 2x/wk for 12wk. Outcomes were assessed at baseline and post-intervention. Outcomes: Spasticity; Berg Balance Scale (BBS); Timed Up and Go test (TUG); Single-task circuit time; dual-task circuit time; dual task cost of walking; digits span forward; digit span backward; Rey Auditory Verbal Learning Test (RAVLT); Continuous Performance Test (CPT); spatial span forward and backward; Trail Making Test (TMT); Verbal Fluency Test (FAS); Quality of Life scale (SF-36). 1. There was a significant time by group effect on spasticity, BBS, TUG, dual-task circuit time, dual-task cot of walking, digits span forward, digits span backward, FAS, and SF-36 pain subscale. 2. There were no significant group by time effects on single-task circuit time, RAVLT, CPT, spatial span forward and backward, TMT, or the SF-36 subscales for physical function and limitation, social function, mental health, emotional problem limitation, vitality, or general perception.</td>
</tr>
<tr>
<td>Population: Experimental Group [EG; N=14]: Mean age=61.2±9.8yr; Gender: Males=11, Females=3. Control Group [CG; N=15]: Mean age=65.7±12.7yr; Gender: Males=11, Females=4. Intervention: The EG performed emphasizing eccentric-overload flywheel resistance exercises with the more-affected lower limb. The CG just continued to follow their daily routine. Training was 2x/wk for 12wk. Outcomes were assessed at baseline and post-intervention. Outcomes: Spasticity; Berg Balance Scale (BBS); Timed Up and Go test (TUG); Single-task circuit time; dual-task circuit time; dual task cost of walking; digits span forward; digit span backward; Rey Auditory Verbal Learning Test (RAVLT); Continuous Performance Test (CPT); spatial span forward and backward; Trail Making Test (TMT); Verbal Fluency Test (FAS); Quality of Life scale (SF-36). 1. There was a significant time by group effect on spasticity, BBS, TUG, dual-task circuit time, dual-task cot of walking, digits span forward, digits span backward, FAS, and SF-36 pain subscale. 2. There were no significant group by time effects on single-task circuit time, RAVLT, CPT, spatial span forward and backward, TMT, or the SF-36 subscales for physical function and limitation, social function, mental health, emotional problem limitation, vitality, or general perception.</td>
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<tr>
<td>Resistance + Aerobic Training</td>
<td>13 stroke patients with a mean time since onset of stroke of at least 9 months and who were independently ambulatory of 15 minutes with or without assistive devices and an activity tolerance of 45 minutes with rest intervals were studied. Patients were randomly allocated to the treatment group that participated in a 10-week training program consisting of a warm-up, aerobic exercises, lower extremity muscle strengthening and a cool down, or to the control group that received no intervention. After the 10 weeks, the control group received 10 weeks of the treatment procedure. The treatment group demonstrated significant improvement on the Nottingham Health Profile (NHP), the adjusted activity (AAS) scale and the Human Activity Profile (HAP) while the control group demonstrated no significant improvement on the outcome measures after the first 10 weeks. All functional performance significantly improved after training for the 13 patients with an improvement in gait speed (28.3%), AAS scores (39.2%), rate of stair climbing (37.4%). The NHP index revealed an average improvement of 77.8% following the training intervention. After training period, total mean peak torque generated by the muscle group of the affected leg significantly increased (42.3%). No significant difference was noted on the affected limb before and after training of muscle tone presents in either the quadriceps or ankle plantarflexor.</td>
</tr>
<tr>
<td>Teixeira-Salmela al. (1999) Canada RCT PEDro=5 TPS&gt;9mo N=13</td>
<td>Population: Experimental Group [EG, N=14]: Mean age=64±7.40yr; Gender: unspecified. Control Group [CG; N=12]: Mean age=63±5.45yr; Gender: unspecified. Intervention: The EG received combined aerobic and resistance training. The control group received unsystematic physical activities or played chess. Training was 60min, 3x/wk for 16wk. Outcomes were evaluated at baseline and 1. There was a significant improvement in the EG compared to the CG on the 6MWT (p&lt;0.001), 10MWT (p&lt;0.001), grip strength, and CSR (p&lt;0.05). 2. There were no significant differences between the EG and CG on the TUG, CS30, or the FRT.</td>
</tr>
<tr>
<td>Lee et al. (2015) Korea RCT PEDro=6 TPS CG=5.98±3.27yr TPS EG=5.83±2.51yr NStart=30 NEnd=26</td>
<td>Population: Experimental Group [EG, N=14]: Mean age=64±7.40yr; Gender: unspecified. Control Group [CG; N=12]: Mean age=63±5.45yr; Gender: unspecified. Intervention: The EG received combined aerobic and resistance training. The control group received unsystematic physical activities or played chess. Training was 60min, 3x/wk for 16wk. Outcomes were evaluated at baseline and 1. There was a significant improvement in the EG compared to the CG on the 6MWT (p&lt;0.001), 10MWT (p&lt;0.001), grip strength, and CSR (p&lt;0.05). 2. There were no significant differences between the EG and CG on the TUG, CS30, or the FRT.</td>
</tr>
</tbody>
</table>
16wk.  
**Outcomes:** 6 Minute Walk Test (6MWT); 10 Metre Walk Test (10MWT); Timed Up and Go test (TUG); grip strength; 30-second chair test (CS30); chair sit reach (CSR); Functional Reach Test (FRT).

### Other

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Time Frame</th>
<th>N</th>
<th>Population</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duncan et al. (1998)</td>
<td>USA</td>
<td>RCT</td>
<td>6</td>
<td>30-90d</td>
<td>20</td>
<td>20 patients with mild to moderate impairment who had completed inpatient rehabilitation and had suffered from stroke 30-90 days were randomized to receive an 8 week (3x/week) home-based exercise program stressing strength, balance and endurance or to a control condition (usual care dictated by physician). Assessments were conducted at baseline, 8 and 12 weeks. Assessments included Fugl-Meyer Score, Barthel Index, Lawton Instrumental ADL, SF-36, 10 metre walk, 6 min walk test, Berg Balance Scale and Jebsen Test of Hand Function.</td>
<td>The only significant difference between the groups at 12 weeks was the Fugl-Meyer Score for the lower extremity, favouring the home-based program group.</td>
<td></td>
</tr>
<tr>
<td>Page et al. (2008)</td>
<td>USA</td>
<td>RCT</td>
<td>4</td>
<td>Chronic</td>
<td>7</td>
<td>In a crossover trial 7 chronic stroke subjects participated in a home-based exercise program. Subjects were randomly assigned to receive: (a) a resistance-based, reciprocal, affected leg locomotor training protocol using the NuStep apparatus and (b) a home exercise programme (HEP) consisting of self-supervised practice with fractionated joint movements of the lower limb. Each phase of the intervention was performed for 30 min, 3days/week x 8 weeks. There was a one-week washout period between phases. The main outcome measures assessed were the lower extremity scale of the Fugl-Meyer (FM) and the Berg Balance Scale (BBS).</td>
<td>The 4 subjects who received the NuStep phase first experienced a 4.3-point gain in FM score and 4 point gain in BBS. Following HEP there were no changes in FM scores and an additional 0.4 gain in BBS. 3 subjects who began in HEP, experienced a 0.75 FM gain and a 1-point loss in BBS scores. After NuStep subjects gain 2.2 points on FM and 4 points on the BBS. Due to small sample sizes, no inferential statistics were conducted.</td>
<td></td>
</tr>
</tbody>
</table>
| Son et al. (2014)  | Korea   | RCT    | 6     | 17.9mo | 28 | Training group (EG; N=14): Mean age=57.4yr; Gender: Males=8, Females=6. Control Group (CG; N=14): Mean age = 56.6yr; Gender: Males=7, Females=7.  
**Intervention:** The EG received the same conservative physical therapy as the CG, and also additionally performed three sets (8 to 10 reps per set) of resistance exercise at 70% of the 1-rep maximum (1RM) to strengthen muscles across multiple joints. Conservative physical therapy for 30 mins per day, 5 days per week, for 6 weeks. Both groups performed the exercises for the same length of time.  
**Outcomes:** Anterior-posterior (A-P); Medio-lateral (M-L) Sway distances; Berg balance scale (BBS); Timed Up- and Go test (TUG). | 1. There were statistically significant changes in A-P and M-L sway distances, BBS scores and TUG times found between groups (p<0.05).  
2. After 6 weeks of intervention, both groups demonstrated statistically significant improvements for BBS scores, A-P and M-L sway distances, and TUG times as indicated by a decrease in these scores, in both groups (p<0.05). |
| Alabdulwahab et al. (2015) | Saudi Arabia | RCT | 6     | 17.9mo | 28 | Mean age: 45.2±12.5yr; Gender: Males=18, Females=5.  
**Intervention:** Participants were randomly assigned to receive the intervention (FLO) or the control group (FCS).  
**Outcomes:** Functional and trunk strength (SGS), functional mobility (FGS), 6min walk test (WBAL), Stoop-Inclination-Sit (SIS) | 1. There was a significant improvement after the treatment in the FLO group on SGS (p=0.004), FGS (p=0.001), WBAL (p=0.018), and SIS |
allocated either to the functional limb overloading (FLO) group where they underwent task-oriented gait training of 1hr duration 3x/wk for 4wk, or to the limb overload resistance training (LORT) group which received a resistance training regime consisting of isotonic exercise using weight cuff tied to ankle or foot. Assessments were conducted before and after treatment.

**Outcomes:** cadence; fast gait speed (FGS); slow gait speed (SGS); weight bearing on affected limb (WBAL); Stroke Impact Scale – Perceived mobility and participation subscales (SIS).

2. There was a significant improvement after the treatment in the LORT group on the SGS (p=0.029), and FGS (p=0.049), but not on cadence, WBAL and SIS.

3. There was a significant difference between groups, with the FLO group outperforming the LORT group on cadence (p=0.024), SGS (p=0.011), FGS (p=0.023), WBAL (p=0.040), and SIS (p=0.046).

### 9.5 Aerobic Exercise

**Table 9.5.1 Summary of Studies Evaluating Aerobic Exercise**

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Katz-Leurer et al.</strong> (2003)</td>
<td>Israel</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&lt;48h</td>
<td>N=92</td>
<td>92 stroke patients were randomly assigned to either an 8-week programme of aerobic training using a leg cycle ergometer or to a control group receiving regular therapy.</td>
<td>Functional abilities improved significantly immediately after intervention in the study group compared to the control group. However, no difference in functional abilities was observed at the 6-month follow up between groups.</td>
</tr>
<tr>
<td><strong>Macko et al.</strong> (2005)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=61</td>
<td>61 chronic stroke patients were randomized to treadmill aerobic exercise program 3x/week for 6 months or to a program of stretching and low-intensity walking.</td>
<td>At the end of 6 months the treadmill training group had made greater gains on the following outcome measures compared to the control group: Peak VO2, 6-minute walk test and the Walking Impairment Questionnaire.</td>
</tr>
<tr>
<td><strong>Letombe et al.</strong> (2010)</td>
<td>France</td>
<td>RCT</td>
<td>PEDro=3</td>
<td>TPS=Acute</td>
<td>N=18</td>
<td>18 hemiparetic, acute stroke patients randomly assigned to either a control group (CG), who underwent 4 weeks of conventional inpatient rehabilitation, or a training group (TG), who performed additional physical exercises, including one-legged cycling. Assessments were conducted before and after treatment and included the maximal aerobic power (MAP) test, peak oxygen consumption and Katz and BI.</td>
<td>Patients in the TG significantly improved their performance on the peak oxygen consumption, MAP and test duration, whereas there was no improvement among patients in the control group. There were no results of between group differences reported. TG patients showed a statistically significant improvement in the BI and Katz ADL scale scores, whereas the pre- and post-rehabilitation values did not differ significantly in the CG. There were no significant differences between groups on either outcome.</td>
</tr>
<tr>
<td><strong>Outermans et al.</strong> (2010)</td>
<td>The Netherlands</td>
<td>RCT</td>
<td></td>
<td></td>
<td></td>
<td>44 patients, 2 to 8 weeks post stroke, were randomized to 1 of 2 circuit-based training programmes 3x/week x 4 weeks. All sessions</td>
<td>Patients in the high-intensity group significantly improved their performance on the 6MWT and the 10MTWT, compared with patients in the low-</td>
</tr>
</tbody>
</table>
were 45 min in length and consisted of 10 standardized work stations. Each lasting 2.5 minutes followed by a 1 min transfer period between stations. 10-minute walking relay races were added at the end of each session. The high-intensity group performed the tasks that focused on postural control and gait-related activities. The goal was to achieve 70-80% of heart rate reserve during each session. The low-intensity group was on improving motor control of the hemiplegic leg. There was no physical fitness component. Outcome measures included maximal gait speed assessed with the 10-metre timed walking test (10MTWT), walking capacity assessed with the six-minute walk test (6MWT). Control of standing balance assessed with the Berg Balance Scale (BBS) and the Functional Reach (FR) test.

**Toledano-Zarhi et al. (2011)**  
Israel  
RCT  
PEDro=6  
TPS=1-3wk  
N=28

28 patients, 1-3 weeks post minor stroke were randomized to an intervention group (supervised exercise training program including treadmill, hand-bike and cycling, 3 hours/week for 6 weeks + home exercise booklet) or to a control group (home exercise booklet only). Outcomes measures assessed were 6-minute walk distance, physiological parameters using the Bruce protocol and Four Square Step test. The intervention group showed a greater improvement in 6MWD (13%) compared to the control group (5%) (p<0.01). No significant change was noted in physiological parameters.

**Globas et al. (2012)**  
Switzerland  
RCT  
PEDro=7  
TPS=Chronic  
N=38

Chronic stroke survivors (n=38; >60 years) with residual hemiparetic gait were randomized to a 3-month (39 session; 3x/week for 3 months) aerobic treadmill exercise (TAEX) group or to a usual care physiotherapy (control) group. The goal for participants in the TAEX group was to achieve 30-50min of training (starting with 10-20min) at 60%-80% of their maximum heart rate reserve (HRR; starting with 40%-50% HRR). Treadmill inclination stayed at 0°. Following the first 3 months, participants in the control group crossed over to receive the TAEX (TAEX-cross) program. The TAEX training was identical to the first group’s training with the exception of treadmill incline, participants trained at an incline of 2%. Primary outcomes included cardiorespiratory fitness (peakVO2) and sustained walking ability (via 6MWT). Secondary outcomes included gait velocity (10MWT), functional leg strength (5-Chair-Rise test; SCR), balance (Berg Balance Scale), mobility and ADL (Rivermead Mobility Index; RMI), and physical and mental health (Medical Outcomes Short-Form 12; SF-12). Following the first 3-months, participants in the TAEX group has statically significant increases in peakVO2 and walking ability compared to the control participants (5.5 ± 1.0 mL/kg/min and 57.7 ± 44.6m, respectively; P<.001). Following the initial first 3-months, there were also significant differences between the TAEX and control participants concerning maximum walking velocity, balance, RMI score, and the mental subscores of the SF-12, with improvements found for participants in the TAEX group. The effects of the TAEX were confirmed by controls crossing over to the TAEX-cross after usual physiotherapy care. Following the cross-over, measures of peakVO2 and walking ability improved significantly (4.4 ± 3.9 mL/kg/min and 57.7 ± 44.6m, respectively; P<.0001). In addition, they showed comparable gains regarding 10MWT, and leg strength measures.

**Jin et al. (2012)**

133 persons with chronic hemiparesis were Significant between group differences favoring the
randomized to either an exercise training group, who received 40 minutes of aerobic cycling exercise, with lower extremity weights, at a target intensity of 50-70% heart rate reserve, 5 days a week for 8 weeks, or, a control group that received low intensity overground walking training at a target heart rate of 20-30% heart rate reserve. Both groups received balance training (30 minutes) and stretching exercises (20 minutes). Primary outcomes included cardiovascular fitness (peak VO\textsubscript{2}) and walking ability (6MWT and the Rivermead Mobility Index). Secondary measures included the Berg Balance Scale, Modified Ashworth Scale and Isokinetic dynamometry for isometric knee muscle strength.

Participants in the intervention group had a higher overall mean score for the Physical Health Component scores compared to the control group ($P=0.024$). In addition, the mean walk distance of the 6MWT was significantly higher at 6-weeks and 3-months for the walking group vs. control ($P<0.001$).

**Population:** Mean age=55±8.2yr; Gender: Male=7, Female=5.

**Intervention:** Participants were randomized to receive either high intensity (HG) or low intensity (LG) lower limb cardiovascular training. All participants completed 12 sessions of their respective programs over 4-5wk followed by a 4wk washout period, at which point participants received the other training program. Outcomes were assessed at baseline and post-training for both periods.

**Outcomes:** Self-Selected Velocity (SSV); Fastest Velocity (FV); 6 Minute Walk Test (6MWT); Peak Treadmill (TM) Speed; Peak Oxygen Uptake (VO\textsubscript{2}).

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>China</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS=Chronic</td>
<td>N=133</td>
<td>randomized to either an exercise training group, who received 40 minutes of aerobic cycling exercise, with lower extremity weights, at a target intensity of 50-70% heart rate reserve, 5 days a week for 8 weeks, or, a control group that received low intensity overground walking training at a target heart rate of 20-30% heart rate reserve. Both groups received balance training (30 minutes) and stretching exercises (20 minutes). Primary outcomes included cardiovascular fitness (peak VO\textsubscript{2}) and walking ability (6MWT and the Rivermead Mobility Index). Secondary measures included the Berg Balance Scale, Modified Ashworth Scale and Isokinetic dynamometry for isometric knee muscle strength.</td>
<td>Gordon et al. (2013)</td>
<td>Jamaica</td>
<td>RCT</td>
<td>PEDro=7</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>RCT</td>
<td>PEDro</td>
<td>TPS</td>
<td>Group 1 (G1, N=16): Mean age=63±2.4yr; Gender: Males=11, Females=5.</td>
<td>Group 2 (G2, N=16): Mean age=63±2.4yr; Gender: Males=11, Females=5.</td>
<td>Outcome 1</td>
<td>Outcome 2</td>
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<td><strong>Intervention:</strong> G1 received higher intensity training, and G2 received lower intensity training. Training was advanced by 5min biweekly to target 30min/d by week 6. Outcomes were evaluated at baseline and post-intervention. <strong>Outcomes:</strong> 6 Minute Walk Time (6MWT); 10 Metre Walk Test (10MWT); 48h Step Counts (48SC).</td>
<td><strong>Intervention:</strong> Patients were randomized to receive conventional rehabilitation alone (CG) or with additional stationary cycling (EG). Both were delivered 30min/d, 5d/wk for 6wk. <strong>Outcomes:</strong> 10-Metre Walk Test (10MWT); Timed Up &amp; Go Test (TUGT); Berg Balance Scale (BBS).</td>
<td><strong>Population:</strong> Experimental Group (EG; N=16): Mean age=61±2.1yr; Gender: Males=3, Females=3.</td>
<td><strong>Population:</strong> Sliding training group (STG; N=20): Mean age=51.4±40.6yr; Gender: Males=10, Females=10. Ergometer bicycle training group (ETG; N=20): Mean age=50.1±7.8yr; Gender: Males=12, Females=8.</td>
<td>1. On BBS, the EG showed significant improvements after treatment (p&lt;0.05), while the CG did not. The EG showed significantly greater improvements on BBS than CG (p&lt;0.05).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>RCT</th>
<th>PEDro</th>
<th>TPS</th>
<th><strong>Outcome 1</strong></th>
<th><strong>Outcome 2</strong></th>
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<td>1.</td>
<td>2.</td>
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</table>

**Song (2015)**

**Outcome 1**

1. Participants in both groups improved significantly on the 10MWT at post-test (both p<0.05).
2. No significant difference in the improvement between the two groups was found.
3. The LOS both in the anterior and in the posterior range increased significantly in both groups at post-test (all p<0.05).
4. Significant differences in the improvements between the two groups were found in the anterior and in the posterior ranges of the LOS (both p<0.05).
**Hornby et al.** (2016)  
USA  
RCT  
PEDro=7  
TPS\(_{EG}\)=114±56d  
TPS\(_{CG}\)=89±44d  
N\(_{Start}\)=33  
N\(_{End}\)=32  

**Population:** Experimental group (EG; N=15): Mean age=57±12yr; Gender: Male=12, Female=3. Control group (CG; N=17): Mean age=60±9.2yr; Gender: Male=12, Female=5.  
**Intervention:** Participants were randomized to receive either high cardiovascular intensity training (EG) or usual care (CG). Participants completed 40, 1hr sessions over 10wk (4-5/wk).  
**Outcomes:** Self-Selected Speed (SSS); Fastest Speed (FS); 6 Minute Walk Test (6MWT); Steps/d; Single-Limb Stance at SSS and FS; Step Symmetry at SSS and FS; Berg Balance Scale (BBS); Sit-to-Stand; Physical Short Form 36 (SF-36); Activities-Specific Balance Coordination (ABC).  
1. EG group showed significantly greater improvements over time in SSS (p=0.002), FS (p=0.006), 6MWT (p=0.001), Single-Limb Stance at SSS (p<0.001) and FS (p=0.002), and Physical SF-36 (p=0.014) compared to the CG group.  
2. There was no significant difference between groups in steps/d (p=0.84), Step Symmetry at SSS (p=0.385) and FS (p=0.172), BBS (p=0.66), Sit-to-Stand (p=0.955), and ABC (p=0.305).

**Sandberg et al.** (2016)  
Sweden  
RCT  
PEDro=6  
TPS\(_{EG}\)=4.9±5.8d  
TPS\(_{CG}\)=6.3±7.3d  
N\(_{Start}\)=56  
N\(_{End}\)=56  

**Population:** Experimental Group (EG, N=29): Mean age=71.3±7.0yr; Gender: Males=14, Females=15. Control Group (CG; N=27): Mean age=70.4±8.1yr; Gender: Males=14, Females=13.  
**Intervention:** The EG received group aerobic exercise sessions. The training sessions were 60min, 2x/wk for 12wk. The CG did not receive organized rehabilitation or scheduled physical exercise. Assessments were done at baseline and post-intervention.  
**Outcomes:** 6 Minute Walk Test (6MWT); 10 Metre Walk Test (10MWT); Timed Up and Go test (TUG); Single Leg Stance (SLS); European Quality of Life Scale (EQ-5D); Visual Analog Scale (VAS); Stroke Impact Scale (SIS).  
1. The EG did significantly better than the CG on the 6MWT (p=0.011), 10MWT (p<0.001), TUG (p<0.001), SLS with eyes open on both legs (p<0.05), SLS with eye closed on the right leg (p=0.019), VAS (p=0.008) and SIS recovery.  
2. There were no significant differences between the EG and the CG on the EQ-5D or SIS participation.

**Wang et al.** (2016)  
China  
RCT  
PEDro=5  
TPS\(_{EG}\)=29±10.1d  
TPS\(_{CG}\)=31±5.2d  
N\(_{Start}\)=42  
N\(_{End}\)=34  
N\(_{1yr}\)=25  

**Population:** Experimental Group (EG, N=21): Mean age=51±6.2yr; Gender: Males=13, Females=8. Control Group (CG; N=21): Mean age=52±11.3yr; Gender: Males=10, Females=11.  
**Intervention:** All participants received a 6wk rehabilitation training program. This training was 5x/wk. The EG received additional low intensity aerobic training 3x/wk. Assessments were done at baseline, post-intervention, and at a 1yr follow-up.  
**Outcomes:** Barthel Index (BI); Functional Ambulation Category (FAC); Frenchay Activities Index (FAI); Fugl-Meyer Assessment (FMA).  
The EG showed significant improvements when compared to the CG on the BI, FMA exercise test, and FAC post-intervention, and significantly higher scores on the FAC ad FAI at 1yr (p<0.05).

**Exercise Program**  
**Rimmer et al.** (2000)  
USA  
PCT  
No Score  
TPS=Chronic  
35 chronic stroke survivors, predominantly African Americans participated in a 12-week outpatient exercise program focusing on cardiovascular conditioning, strength and flexibility training. Sessions lasted for 1 hour, 3 x  
Compared with controls, the exercise group showed significant gains in peak VO2, strength, lower limb flexibility and body composition (body weight and BMI). There was no significant difference between exercise and controls on

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9. Mobility and the Lower Extremity  
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<th>Study</th>
<th>Location</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Participant Characteristics</th>
<th>Intervention</th>
<th>Main Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green et al. (2002)</td>
<td>UK</td>
<td>RCT</td>
<td>8</td>
<td>N=72</td>
<td>Community based supervised program involving 1.5 hour sessions 3x/wk for 19 weeks.</td>
<td>There was a difference in Rivermead mobility index (RMI) scores at 3 months, after adjusting for differences in baseline gait speed. However, there were no longer differences in RMI scores between the groups at 6 or 9 months. Treatment had no effect on patients’ daily activity, social activity, anxiety, depression, and number of falls, or on emotional stress of carers.</td>
</tr>
<tr>
<td>Duncan et al. (2003)</td>
<td>USA</td>
<td>RCT</td>
<td>8</td>
<td>N=63</td>
<td>Intention-to-treat multivariate analysis of variance testing the overall effect demonstrated that the intervention produced greater gains than usual care. Gains for the intervention group exceeded those in usual care group in balance, endurance, peak aerobic capacity and mobility. The authors concluded that the structured, progressive program of therapeutic exercise in persons who had completed acute rehabilitation services produced gains in endurance, balance and mobility beyond those attributable to spontaneous recovery and usual care.</td>
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</tr>
<tr>
<td>Pang et al. (2005)</td>
<td>Canada</td>
<td>RCT</td>
<td>7</td>
<td>N=63</td>
<td>The intervention group achieved greater gains than the control group at the end of the treatment period on the following outcome measures: maximal oxygen consumption, distance on the 6-minute walk test, paretic leg muscle strength, paretic femoral neck bone mineral density. There were no differences between the groups in: Berg Balance scores, respiratory exchange ratio, Physical Activities for Individuals with Physical Disabilities (metabolic equivalent h/d).</td>
<td></td>
</tr>
<tr>
<td>Olney et al. (2006)</td>
<td>Canada</td>
<td>RCT</td>
<td>7</td>
<td>N=72</td>
<td>After 1-year significant improvement was achieved by both groups for the 6-min walking speed and the SF-36 Physical Component summary Scale. For the Human Activity Profile, the unsupervised group scores declined after 10 wks, whereas the supervised group reached significant improvement by 1 year. Only the unsupervised group achieved significant improvements in the Physiological Cost Index by 1 year. There were no significant between-group differences.</td>
<td></td>
</tr>
<tr>
<td>Dean et al. (2012)</td>
<td>Australia</td>
<td>RCT</td>
<td>7</td>
<td>N=151</td>
<td>At 12 month follow up, the experimental group showed significant improvement in 6-MWT (Cl=19-50: P&lt;0.001) and gait speed (Cl=0.01-0.14: P=0.03). The experimental group had 129 falls compared to 133 falls by the control group. There were no significant differences in the Berg Balance score, SF-36 physical component summary scale, 6MWT or Rivermead mobility index (RMI). The intervention group showed a trend toward lower scores on the anxiety and depression subscales of the Hospital Anxiety and Depression Scale, and the physical activity subscale of the Physical Activities for Individuals with Physical Disabilities (metabolic equivalent h/d) scale.</td>
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</tbody>
</table>

9. Mobility and the Lower Extremity  
[www.ebrsr.com](http://www.ebrsr.com)
N=151  
and cognitive tasks. The primary outcome measures were the number of falls and characteristics of mobility including the 6-MWT and 10-m Walk test. Secondary outcome measures were falls risk score, habitual physical activity, QOL, community participation, and health system contact.  
were no differences in the proportion of fallers or the rate of falls between groups.

**Mayo et al.** (2013)  
Canada  
RCT  
PEDro=6  
TPS<12mo  
N=87  
This study investigated the effectiveness of two home-based exercise programs for improving walking ability in stroke survivors. Eighty-seven survivors who had completed formal rehabilitation were randomized to either a stationary cycle or walking and exercise group. Programmes differed only by mode of exercise. Each program lasted 12-months. Participants were instructed by trained individuals on how to perform a standardized activity program (activities, duration, and intensity to be performed daily), specific to their group assignment. Therapists visited participants 13 times over the course of the year, and participants tracked their activity (duration and intensity) via a log book. The primary outcome was distance walked in six minutes (6MWT), which was assessed at baseline, one-, six-, and 12-months.  
There were no significant effects of group, time, or the interaction between group and time found for the 6MWT. Overall, both programs (stationary cycling and walking/exercise) were found to be equally effective (or equally ineffective in maintaining walking capacity over the 12-month period.

**Kim et al.** (2014)  
Korea  
RCT  
PEDro=8  
TPS_CWTP=190.45d  
TPS_CG=272.82d  
N_Start=26  
N_End=22  
Population: Community walking training program (CWTP; N=11): Mean age=50.18±10.29yr; Gender: Male=6, Females=5. Control Group (CG; N=11): Mean age=50.73±7.24yr; Gender: Males=7, Females=4.  
Intervention: Participants were randomly allocated either to the community walking training program (CWTP) group and participated (30 minutes per day, 5 times a week, for 4 weeks), or to the CG (CG) which did not participate in the social walking intervention. All participants received standard rehabilitation for 60 mins per day, 5 times by week, for 4 weeks. Assessments were conducted before and after the intervention period.  
Outcomes: 10-meter Walking Test (10MWT) (speed); 6 Minute Walk Test (6MWT); Stroke Impact Scale (SIS); Community walking test (time).  
1. The CWTP group and the CG improved significantly on the 10MWT (CWTP group: ΔM=0.19; CG: ΔM=0.07; both p<0.05), 6MWT (CWTP group: ΔM=65.20; CG: ΔM=17.98; both p<0.05), and on the SIS (CWTP group: ΔM=12.49; CG: ΔM=4.25; both p<0.05).  
2. Only the CWTP group improved on the community walk test (ΔM=-13.46, p<0.05).  
3. A significant difference in the improvements between the two groups was found on the 10MWT (p=0.045), 6MWT (p=0.004), community walking test (p=0.014), and on the SIS (p=0.023).  

**Taricco et al.** (2014)  
Italy  
PCT  
No Score  
TPS_APA=287.3d  
TPS_CG=194.1d  
Population: Adapted physical activity group (APA; N=126): Mean age=71.8±10.5yr; Gender: Males=85, Females=41. Control Group (CG; N=103): Mean age=70.1±10.7yr; Gender: Males=62, Females=41.  
Intervention: The APA group received 16 APA

1. The APA group improved significantly on the 6MWT (p=0.002), BBS (p<0.001), SPPB (p<0.001), MI (p=0.001), GDS (p<0.001), and the SF-12 (p<0.001).  
2. The CG showed no significant improvement on either of the outcome measures.
sessions and 3 sessions of therapeutic patient education (TPE), while the control group received usual care only. Participants were allocated either to the EG and received 16 adapted physical activity (APA) sessions and 3 therapeutic patient education (TPE) sessions, or to the CG and received usual care. Assessments were conducted before and after the intervention.

**Outcomes:** 6 Minute Walk Test (6MWT); Modified Barthel Index (MBI); Mini-Mental State Examination (MMSE); Disability Communication Scale (DCS); CIRS; SPPB; BBS; MI; Geriatric Depression Scale (GDS); Caregiver Strain Index (CSI); Short Form Health Survey (SF-12).

3. A significant difference between groups was found 6MWT (p=0.01), BBS (p<0.001), SPPB (p<0.001), and on the physical composite scale of the SF-12 (p<0.001).

4. No significant difference was found on the remaining scales.

### Table 9.6.1 Summary of Studies Evaluating Wheelchair Mobility

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N start</th>
<th>N end</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marsden et al. (2016)</td>
<td>Australia</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS&lt;sub&gt;EG&lt;/sub&gt;=5.6±5.3mo</td>
<td>TPS&lt;sub&gt;CG&lt;/sub&gt;=3.8±1.2mo</td>
<td>N&lt;sub&gt;start&lt;/sub&gt;=20</td>
<td>N&lt;sub&gt;end&lt;/sub&gt;=20</td>
<td>Mean age=54.4±22.2yr, Gender: Males=3, Females=7. Control Group (CG; N=10): Mean age=62.0±16.8yr, Gender: Males=5, Females=5.</td>
<td>Both the EG and CG received usual care. In addition, the EG took part in a 12wk, individually tailored, home- and community-based exercise program. Assessments were done at baseline and 12wk.</td>
</tr>
<tr>
<td>Moore et al. (2016)</td>
<td>UK</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS=19±26mo</td>
<td>N&lt;sub&gt;start&lt;/sub&gt;=40</td>
<td>N&lt;sub&gt;end&lt;/sub&gt;=40</td>
<td>Mean age=69±9yr, Gender: Males=34, Females=6.</td>
<td>Participants were randomized to the experimental group (EG; N=20): 19wk (3x/wk) progressive mixed (aerobic, strength, balance, flexibility) community group exercise program, or the control group (CG; N=20): matched duration home stretching program.</td>
<td>1. The EG improved significantly compared to the CG on the 6MWT and step test (p&lt;0.05). 2. There were no significant differences between the EG and CG on the SWT, cPXT, 10MWT, FAS, PHQ-9, and SAQOL.</td>
</tr>
</tbody>
</table>

### 9.6 Assistive Devices

#### 9.6.1 Wheelchair
9.6.2 Walking Aid

Table 9.6.2 Summary of Studies Evaluating Walking Aids

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laufer (2002) Israel RCT PEDro=5 TPSmean=77.7±61.7 N=50</td>
<td>30 hemiparetic stroke patients and 20 health controls were studied. Patients were tested on 2 force plates under 3 conditions: with no cane, one-point cane and with a 4-point cane. Testing was 30 seconds long, given in random order. Patients were measured by weight born by lower extremities and by the walking aids expressed as a percentage of overall body weight, and by Sway Index.</td>
<td>In both the aligned and the unaffected extremity placed forward (FW) position, postural sway was reduced only with the quad cane. Both types of canes reduced postural sway in the affected FW position; however, the quad cane had a greater effect. An asymmetrical weight between the lower extremities did not change in the patient group across positions, even with walking aids. A quad cane appears to be more effective than a standard cane in decreasing postural sway in...</td>
</tr>
</tbody>
</table>
patients with moderate impairment secondary to hemiparesis. The greatest effect on postural sway occurred when the assistive device was contralateral to the foot placed forward. The use of a cane does not appear to adversely affect the asymmetrical weight-bearing pattern during stance that is characteristic of patients with hemiparesis, even when balance is challenged by decreasing the base of support.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS Initiation</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeong et al. (2015)</td>
<td>Korea</td>
<td>RCT</td>
<td>7</td>
<td>TPS Initiation</td>
<td>N=15</td>
<td>N=15</td>
<td>Poor Balance (PB; N=15): Mean Age=55.30yr; Gender: Male=8, Female=7</td>
<td>Groups divided based on Berg-Balance scale. All patients performed walking tests (in outcomes) for 3 consecutive days using a single point cane, a quad cane or a hemi-walker. Patients were randomized to order of cane use and all patients used all 3 canes across the intervention period.</td>
<td>10m walking test (10MWT); 6min walk test (6MWT).</td>
<td>1. Significantly higher gait velocity in the GB group when using the single point cane compared to the quad cane and hemi-walker (single point=0.42m/s, quad point=0.30m/s, hemi=0.27m/s, p&lt;0.01), no effect of cane type on gait velocity in PB group (p=0.25).</td>
</tr>
<tr>
<td>Cha (2015)</td>
<td>Korea</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS Initiation</td>
<td>N=9</td>
<td>N=9</td>
<td>Overall mean age=58.4±10.6; Gender: Males=7, Females=9</td>
<td>G1 walked with a cane fitted to the height of the greater trochanter (GT), and G2’s cane was fitted to the wrist crease. The participants gait velocity was evaluated using a pressure plate embedded in a 5m walkway.</td>
<td>Gait velocity.</td>
<td>1. There was no significant difference between the gait velocity of G1 and G2.</td>
</tr>
<tr>
<td>Morone et al. (2016)</td>
<td>Italy</td>
<td>RCT</td>
<td>6</td>
<td>TPS Initiation</td>
<td>N=21</td>
<td>N=21</td>
<td>Experimental Group (EG, N=21): Mean age=61.50±10.97yr; Gender: Males=16, Females=5</td>
<td>All participants received 20 sessions of standard therapy. The other 20 sessions the participants in the EG trained with the i-Walker, and the CG received conventional walking therapy. Sessions were 40min, 2x/d, 5d/wk, for 4wk. Outcomes were analyzed before and after the intervention as well as a 6mo follow-up to measure the number of falls.</td>
<td>Tinetti Scale (TI); 10 Metre Walking Test (10MWT); 6 Minute Walking Test (6MWT); Ashworth Scale (AS); Functional Ambulation Category (FAC); Barthel Index (BI); Canadian Neurological Scale (CNS).</td>
<td>1. There was a significant group and time interaction on the 10MWT (p=0.001) and the 6MWT (p=0.008).</td>
</tr>
<tr>
<td>Nascimento et al. (2016)</td>
<td>Brazil</td>
<td>RCT</td>
<td>No Score</td>
<td>TPS Initiation</td>
<td>N=6</td>
<td>N=6</td>
<td>Slow Group (N=6): Mean age=70±9yr; Gender: Males=4, Females=2.</td>
<td>There was a significant increase in gait velocity and step length (p&lt;0.05) but not</td>
<td></td>
<td>1. There was a significant increase in gait velocity and step length (p&lt;0.05) but not</td>
</tr>
</tbody>
</table>
9.6.3 Ankle Foot Orthosis

Table 9.6.3.1 Summary of RCTs Evaluating Ankle Foot Orthosis

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen et al. (1999)</td>
<td>China</td>
<td>RCT</td>
<td>PEDro=3</td>
<td>TPS\text{median}=13mo</td>
<td>N=24</td>
<td>24 patients took the postural stability test while wearing an AFO and not wearing AFO. Patients were randomized to first one treatment and then the other and tested for both.</td>
<td>When wearing the AFO, there was no significant difference with small effect size in postural sway index, postural symmetry and maximal balance range in the anterior-posterior direction. There was a significant improvement and a large effect size in lateral weight shifting and weight bearing through the affected leg after weight shifted to the affected side.</td>
</tr>
<tr>
<td>de Wit et al. (2004)</td>
<td>Netherlands</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS\text{Chronic}</td>
<td>N=20</td>
<td>20 chronic stroke patients who had been wearing an AFO for at least six months were assessed with and without their AFO included, the order of which was randomized. Evaluations included: comfortable walking speed, scores on the timed up and go (TUG) test and stairs test. Clinically relevant differences based on literature were defined for walking speed (20 cm/s), the TUG test (10s).</td>
<td>The mean differences between groups were significant in favour of the AFO condition in the TUG test 3.6 sec (95% CI 2.4-4.8) and in the stairs test 8.6 sec (95% CI 3.1-14.1), although the differences were not clinically significant. 70% of the patients reported feeling more self-confident while wearing the AFO.</td>
</tr>
<tr>
<td>Pohl &amp; Mehrholz (2006)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS\text{Chronic}</td>
<td>N=28</td>
<td>20 stroke patients (with an additional 8 traumatic brain injury patients) were randomly assigned to wearing ankle-foot orthoses (AFO) for varying sequences or wearing only footwear. Evaluations included gait parameters with ground reaction forces and stance parameters.</td>
<td>There was a significant reduction of postural sway with eyes opened and greater improvement of stance symmetry for the AFO group compared with the no AFO group. Also, significant between-group differences were seen for 3 gait parameters: stance duration at 90% body-weight (vertical ground reaction forces), deceleration forces (horizontal ground reaction forces and double stance duration).</td>
</tr>
<tr>
<td>Wang et al. (2007)</td>
<td>Taiwan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>58 stroke patients with hemiparesis of duration of less than 6 mos were evaluated for the</td>
<td>Measures of balance (% weight bearing difference, movement velocity, measured in</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Country</td>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Intervention</td>
<td>Population</td>
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</tr>
<tr>
<td>Tyson &amp; Rogerson (2009)</td>
<td>Crossover RCT</td>
<td>UK</td>
<td>6</td>
<td>&gt;6mo</td>
<td>58</td>
<td>20 nonambulatory stroke rehabilitation inpatients were fitted with, and given the opportunity to practice walking with several assistive devices. Their walking ability was assessed with each of them, in random order: (1) Walking with no device (the control condition), (2) walking with a walking cane, (3) ankle foot orthosis, (4) slider shoe, and (5) a combination of all 3 devices. On a single testing time, the following outcomes were assessed: Functional mobility (functional ambulation categories-FAC), walking impairments (speed, step length of the weak leg), and patients’ opinions.</td>
<td>Males=9, Females=1.</td>
</tr>
<tr>
<td>De Seze et al. (2011)</td>
<td>RCT</td>
<td>France</td>
<td>5</td>
<td>6mo</td>
<td>28</td>
<td>28 patients from 7 rehabilitation facilities with hemiplegia following a stroke within 6 months were randomized to wear either a standard AFO (n=15) or to wear a Chignon ankle-foot orthosis (n=8) for the duration of the study. The Chignon ankle-foot orthosis is an articulated double-stopped custom-made orthosis with elements to assist dorsiflexion and plantar flexion. Gait speed improvement was assessed at day 0, 30 and 90 by examining the ratio of the time to perform the 10-metre walk test with and without the orthosis.</td>
<td>N=32</td>
</tr>
<tr>
<td>Erel et al. (2011)</td>
<td>RCT</td>
<td>Turkey</td>
<td>5</td>
<td>6mo</td>
<td>32</td>
<td>32 subjects with a maximum MAS score of 3, at least 6 months following stroke and scored 3-5 on the Functional Ambulation Classification were randomized to wear a dynamic ankle-foot orthosis or not for 3 months. Outcomes assessed included Functional Reach, timed up and go, Time up stairs, time down stairs, gait velocity and Physiological Cost Index.</td>
<td>N=28</td>
</tr>
<tr>
<td>Kim et al. (2015)</td>
<td>PCT</td>
<td>Korea</td>
<td>No Score</td>
<td>19-130mo</td>
<td>20</td>
<td>Population: Mean age=55.7±8.4yr; Gender: Males=9, Females=1. Intervention: Participants completed postural stability testing under each of the three experimental conditions: N-AFOs, P-AFOs, and E-AFOs. Three trials were completed for each condition. Outcomes: Overal Stability Index (OSI); Anterior or-posterior stability index (ASPI); medial-lateral stability index (MLSI); location of the centre of balance (COB); time spent on each limb.</td>
<td>N=10 N=10</td>
</tr>
</tbody>
</table>

9. Mobility and the Lower Extremity
Momosaki et al. (2015)  
Japan  
Case Control  
No Score  
TPS$_{AFO}$=32.5±16.6d  
TPS$_{No\ AFO}$=33.0±17.4d  
N$_{Start}$=1862  
N$_{End}$=792  
**Population:** Ankle-Foot Orthosis Group (AFO; N=396): Mean age=67.8±13.4yr; Gender: Males=226, Females=170. No Ankle-Foot Orthosis Group (No AFO; N=396): Mean age=65.7±31.4yr; Gender: Males=226, Females=170.  
**Intervention:** The AFO group was prescribed an AFO to be used during therapeutic exercises and the No AFO group did not get an AFO. Exercises were performed 20-30min/d, 5-7x/wk. Outcomes were evaluated at discharge.  
**Outcomes:** Functional Independence Measure (FIM).  

### Results

1. AFO group had significantly higher scores than the No AFO group in discharge FIM (p=0.02), FIM gain (p<0.001), and FIM efficiency (p<0.001).

Pardo et al. (2015)  
USA  
PCT  
No Score  
TPS$_{Mean}$=13.5±3.3mo  
N$_{Start}$=14  
N$_{End}$=14  
**Population:** Mean age=55.7±4.3yr; Gender: Males=9, Females=5.  
**Intervention:** Patients were assessed under three different conditions: wearing their own C-AFO, wearing the P-AFO that had the best fit, and no AFO. Participants were then assessed in a series of gait and functional mobility test. Once the participants finished all the tests under one condition, they immediately went into the second condition.  
**Outcomes:** Gait velocity; stride length; maximal step length (MSL); Timed Up and Go Test (TUG); Sit-to-Stand (STS).

### Results

1. There were no significant differences in gait velocity, stride length, TUG, MSL or STS when wearing the C-AFO or the P-AFO.  
2. There were significant differences in gait velocity, stride length, TUG, and MSL were observed between the shoes-only and braced conditions.

Bouchalova et al. (2016)  
Belgium  
PCT  
No Score  
TPS=16.67±23.84mo  
N$_{Start}$=15  
N$_{End}$=15  
**Population:** Mean age=59.40±9.32yr; Gender: Males=12, Females=3.  
**Intervention:** Participant were sorted into groups based on their performance on the Timed Up and Go test. Those who completed it in less than 20s were put in the without AD group, and those who took longer than 20s were in the AD group. Each participant was tested in three difference conditions: with standard prefabricated ankle-foot orthosis (Maramed), individualized ankle-foot orthosis, and without ankle-foot orthosis.  
**Outcomes:** Single support time; double support time; gait velocity; cadence; step length.

### Results

1. The Maramed users did significantly better than the participants without an AFO on single support time on the affected side at a moderate speed (p<0.05).  
2. The Y-Tech users did significantly better than the participants without an AFO at fast walking speeds on gait velocity; cadence, single support time on the affected side, and step length.  
3. At their usual walking speed, the Y-Tech users did significantly better than the participants with an AFO on single support time on the affected side, and step length.

Pomeroy et al. (2016)  
UK  
RCT  
PEDro=8  
TPS$_{EG}$=22.2±26.7d  
TPS$_{CG}$=19.5±11.3d  
N$_{Start}$=105  
N$_{End}$=105  
**Population:** Experimental Group (EG; N=51): Mean age=69.1±13.6yr; Gender: Males=26, Females=25. Control Group (CG; N=54): Mean age=64.2±15.3yr; Gender: Males=37, Females=17.  
**Intervention:** All participants received conventional physical therapy than included use of time spent on the non-paretic leg with N-AFO.

### Results

1. There were no significant differences between the groups in gait velocity, FAC, or MRMI at 6wk or 6mo.
of “off-the-shelf” and orthotist-made AFOs. The EG also received a SWIFT cast for up to 6wk. Assessments were done at baseline, 6wk, and 6mo

**Outcomes:** Gait velocity; Functional Ambulatory Categories (FAC); Modified Rivermead Mobility Index (MRMI).

### 9.6.4 Taping

#### Table 9.6.4.1 Summary of Studies Evaluating Taping

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Choi et al. (2013) | Korea | RCT | PEDro=5 | TPS=NA | N<sub>Start</sub>=30 N<sub>End</sub>=30 | Population: No population demographics were reported in this study.  
**Intervention:** The EG was applied taping before therapeutic exercise, and then underwent therapeutic exercise. The CG received only therapeutic exercise (without taping).  
**Outcomes:** Berg Balance Scale (BBS); 10-m walking test (10MWT); Straight line walking test (SWT). | 1. The EG exhibited statistically significant differences in their results for the SWT and the 10MWT (p<0.05).  
2. There were no statistically significant differences in the results of SWT, BBS, and 10MWT for the CG. There were statistically significant differences between groups with respect to the BBS and 10MWT (p<0.05). |
| Kim et al. (2014) | RCT | PEDro=5 | TPS=Subacute | N<sub>Start</sub>=30 N<sub>End</sub>=30 | Population: Not reported.  
**Intervention:** Patients were randomized to receive therapeutic exercise alone (control) or with kinesio-taping (treatment).  
**Outcomes:** Berg Balance Scale (BBS); 10-Metre Walk Test (10MWT); Straight Line Walk Test (SLWT). | 1. Treatment group demonstrated significant improvements on 10MWT and SLWT after treatment (p<0.05).  
2. Control group did not demonstrate significant improvements on any outcome after treatment.  
3. Improvement on 10MWT and SLWT was significantly greater in the treatment group than control group (p<0.05). |
| Nam et al. (2015) | Korea | RCT | PEDro=5 | TPS<sub>EG</sub>=24.2±11.3mo TPS<sub>CG</sub>=28.2±11.6mo | N<sub>Start</sub>=30 N<sub>End</sub>=30 | Population: Experimental Group (EG, N=15): Mean age=64.4±10.9yr; Gender: Males=7, Females=8. Control Group (CG; N=15): Mean age=65.3±5.8yr; Gender: Males=9, Females=6.  
**Intervention:** The EG preformed mat and treadmill training with non-elastic tape applied to the lower extremities and the control group performed the same exercises but without taping. Training was 3x/wk for 6wk.  
**Outcomes:** Berg Balance Scale (BBS); Timed Up and Go test (TUG); stance duration; swing duration; stride duration. | 1. There were significant differences found between the EG and the CG on the BBS and TUG (p<0.05).  
2. There were no significant differences between the groups on the stance duration, swing duration, and stride duration. |
### Table 9.5.6.1 Summary of Studies Evaluating End-Effector Devices

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gait Trainer</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Werner et al. (2002)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Subacute</td>
<td>30 subacute, nonambulatory stroke patients with Functional Ambulation Category (FAC) scores less than 3 were randomized to receive 2 weeks of locomotor therapy on: a gait trainer (A) and treadmill therapy with body weight support (B). Group 1 treatment order was A-B-A and Group 2 treatment order was B-A-B.</td>
<td>FAC, gait velocity and Rivermead scores improved significantly in both groups. Group 1 reached significantly better gait ability level at the end of the study period.</td>
</tr>
<tr>
<td>Peurala et al. (2005)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>45 ambulatory chronic stroke subjects were randomized to 3 groups: 1) gait trainer (with BWS) exercise with functional electric stimulation (GTstim), 2) gait trainer (with BWS) exercise without stimulation (GT), and 3) walking overground (WALK). All patients practiced gait for 15 sessions during 3 weeks (each session, 20 min), and received additional physiotherapy 55 minutes daily. Outcome measures included: ten-meter walk test (10MWT), six-minute walk test (6MWT), lower-limb spasticity and muscle force, postural sway tests, Modified Motor Assessment Scale (MMAS), and FIM instrument scores were recorded before, during, and after the rehabilitation and at 6 months follow-up.</td>
<td>The mean walking distance at the end of treatment period was greatest for patients in the GTstim and GT groups,(6900 and 6500 vs. 4800 m) The body-weight support was individually reduced from 30% to 9% of the body weight over the course of the program. The 10MWT, 6MWT, MMAS, dynamic balance test time and test trip (P=.005) scores improved similarly for all patients, regardless of group assignment. However, no differences were found between the groups. Patients' motor performance remained improved at the follow-up.</td>
</tr>
<tr>
<td>Tong et al. (2006)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Acute</td>
<td>46 acute stroke patients were randomly assigned to 1 of 3 groups: i.) conventional gait training (CGT) (n=20), ii.) gait training using an electrical gait trainer with partial body weight support (EGT) (n=15), or iii.) gait training using an electromechanical gait trainer with functional electric stimulation (EGT-FES) (n=15). Each group received 40 min of regular physiotherapy. The experimental treatment was given 20 min/day, 5 days/wk for 4 weeks. Outcome measures included five-meter walking speed test, elderly mobility scale (EMS), Motricity Index (MI) leg subscale, functional ambulatory category (FAC), Berg Balance Scale (BBS) BI and FIM.</td>
<td>Patients in all 3 groups demonstrated improvements over time in all outcomes assessed. Patients in both gait trainer groups (with and without FES) had better FAC scores and faster walking speed at the end of 2 and 4 weeks compared with patients in CGT groups. MI scores were significantly higher for patients in the gait training groups at 4 weeks. No significant differences among groups on BBS, BI or FIM</td>
</tr>
<tr>
<td>Dias et al. (2007)</td>
<td>Portugal</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>40 chronic stroke subjects were randomised to two groups: the control group (CG) that used the Bobath method in 40 minutes sessions, 5 times a week, for 5 weeks, and the experimental group (EG) that used the gait trainer, for the same</td>
<td>CG and EG showed significant improvement in most of the assessment scales after treatment. At 3 months, subjects in the EG had sustained a significantly greater proportion of their gains compared with the CG. There were no</td>
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<tr>
<td>Study Authors</td>
<td>Location</td>
<td>Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>N</td>
<td>Summary</td>
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<tr>
<td>N=40</td>
<td>period of time and frequency. Assessment tools: Motricity Index (MI); Toulouse Motor Scale (TMS); modified Ashworth Spasticity Scale (mASS); Berg Balance Scale (BBS); Rivermead Mobility Index (RMI); Fugl-Meyer Stroke Scale (FMSS); Functional Ambulation Category (FAC); Barthel Index (BI); 10 meters, time up and go (TUG), 6 minutes, and step tests. Assessments were conducted before and after treatment and at 3-months follow-up.</td>
<td>statistically significant differences between groups.</td>
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<tr>
<td>Pohl et al. (2007)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS&lt;60d</td>
<td>N=155</td>
<td>155 stroke patients admitted to a stroke rehabilitation unit were randomized to receive either 20 min of repetitive practice on a gait trainer, followed by 25 min of individual PT everyday for 25 min for four weeks (group A) or 45 min of individual PT (group b). Total treatment time was identical between groups. Outcomes, assessed at the end of treatment and 6 months included gait ability and ADL function.</td>
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<tr>
<td>Ng et al. (2008)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS&lt;6wk</td>
<td>N=54</td>
<td>Addition of 4 subjects to study authored by Tong et al. (2006)</td>
</tr>
<tr>
<td>Peurala et al. (2009)</td>
<td>Finland</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPSmean=8d</td>
<td>N=56</td>
<td>56 patients, a mean of 8 days post stroke, participated in a 3-week inpatient rehabilitation program and were randomized to one of three groups: 1) gait trainer exercise with BWS; 2) walking training over ground with 1 or 2 physiotherapists; or 3) conventional treatment. Patients in the gait trainer exercise and walking groups practiced gait for 15 sessions over 3 weeks and received additional physiotherapy. Functional Ambulatory Category (FAC) and several secondary outcome measures assessing gait and mobility were administered before and after rehabilitation and at 6-month follow-up. Patients also evaluated their own effort.</td>
</tr>
<tr>
<td>Morone et al. (2011)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Subacute</td>
<td>N=48</td>
<td>48 participants with motor and gait dysfunction were stratified by the Motricity Index into high (&lt;29) and low (&gt;/=29) impairment groups. Each arm was randomized to a robotic or control group (RG or CG) at a mean of 20 days after stroke. All patients underwent 2 therapy sessions per day, 5 days per week for 3 months. Those in the RG underwent 20 sessions of robotic-assisted gait training in the first 4 weeks of inpatient therapy</td>
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using controlled endpoint trajectories and abbreviated conventional therapy, whereas the CG received only conventional gait training. The primary outcome was the functional ambulation category (FAC), and secondary measures were the Rivermead mobility index (RMI) and 6-minute walking distance, all evaluated at hospital admission and at discharge. Follow-up assessments at 2 years were also conducted.

<table>
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<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Hesse et al. (2012)</td>
<td>Germany</td>
<td>RCT</td>
<td>6</td>
<td>Subacute</td>
<td>30</td>
<td>Thirty non-ambulatory subacute stroke patients were allocated to one of two treatment groups (intervention vs. control). Participants in both groups received individual physiotherapy (PT) every workday for 4 weeks. The PT sessions emphasized restoration and improvement of gait and stair climbing by applying a task-specific repetitive approach in conjunction with tone-inhibiting maneuvers. PT sessions for individuals in the control group lasted for 60min, in contrast to individuals in the intervention group in which PT session duration was 30min, preceded by 30min of therapy time on the G-EO System (a gait robot offering repetitive practice of simulated floor walking and stair climbing). The primary outcome variable was the Functional Ambulation Categories (FAC) score. Secondary variables included: the Rivermead Mobility Index (RMI), 10m walk test (gait velocity), lower-limb Motricity Index (MI), and lower limb tone via the lower-limb Resistance to Passive Movement Scale. All measures were obtained at baseline, the end of intervention (4 weeks) and 3 months post-intervention.</td>
<td>Over time (baseline to follow-up) patients in both groups showed significant improvements on FAC scores, gait velocity, RMI, and MI scores. Larger improvements were found for patients in the intervention group regarding the FAC scores, gait velocity, RMI, and MI scores. At follow-up FAC scores and MI scores demonstrated a superior training effect in favor of the intervention group.</td>
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<td>Dundar et al. (2014)</td>
<td>Turkey</td>
<td>Case-Control</td>
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<td>Population: Robotic Training and physiotherapy (RT; N=36): Mean age=66.5 ±10.6 yr; Gender: Males=21, Females=15. Conventional Physiotherapy (CP; N=71): Mean age=65.4±12.0yr; Gender: Males=42, Females=29.</td>
<td>Intervention: The experimental group was robotic training (RT) combined with conventional physiotherapy (CP). The RT that the patients received was the Lokomat, 2 times per week for 6 or more weeks) for at least 30 sessions. The comparator group was conventional physiotherapy (CP). This was a 60-minute program, shared by both groups. Outcomes: modified Ashworth Spasticity Scale (MAS); Berg Balance Scale (BBS); Functional Ambulation Category (FAC).</td>
<td>1. For all outcome measures except lower extremity in MAS scores, there was a statistically significant observed in both groups at discharge compared to pre-treatment values. 2. There were no statistically significant between group differences in BBS, MAS and FAC. 3. There were statistically significant between group differences in the lower extremity categories of the BRS, that is, the RT group did better than the CP group.</td>
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<td>Ochi et al. (2015)</td>
<td>Japan</td>
<td>RCT</td>
<td></td>
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<td>Population: Experimental Group (EG; N=13): Mean age=61.8±7.5yr; Gender: Males=11, Females=2. Control Group (CG; N=13): Mean</td>
<td>1. At 4 weeks post-intervention, patients from both groups demonstrated improvements in lower extremity function</td>
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9. Mobility and the Lower Extremity

### Summary of Studies Evaluating Exoskeletal Devices

<table>
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<tr>
<th>Study Authors</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>TPS Overall</th>
<th>TPS EG</th>
<th>TPS CG</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bae et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>6</td>
<td>12.24±6.21mo</td>
<td>11.56±2.60mo</td>
<td>14.22±5.76mo</td>
<td>34</td>
<td>34</td>
<td>Experimental Group (EG; N=17): Mean age=55.25±8.47yr; Gender: Males=11, Females=6. Control Group (CG; N=17): Mean age=56.1±8.02yr; Gender: Males=12, Females=5.</td>
<td>EG received heart rate reserve-guided high-intensity robot-assisted gait training (RAGT), and the CG received ratings of perceived exertion-guided high intensity RAGT. Training was 30min/d, 3x/wk, for 6wk. Assessments were done at baseline and post-intervention.</td>
<td>The EG did significantly better than the CG on both the FMA-LE and 10MWT (p&lt;0.05).</td>
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<tr>
<td>Bang &amp; Shin (2016)</td>
<td>Korea</td>
<td>RCT</td>
<td>7</td>
<td>11.56±2.60mo</td>
<td>12.56±2.65mo</td>
<td>12.9±7.4d</td>
<td>18</td>
<td>18</td>
<td>Experimental Group (EG; N=9): Mean age=53.56±3.94yr; Gender: Males=5, Females=4. Control Group (CG; N=9): Mean age=53.67±2.83yr; Gender: Males=4, Females=5.</td>
<td>EG received robot-assisted gait training and the CG received treadmill training. Training was 1hr/d, 5x/wk, for 4wk. Outcomes were evaluate at baseline and post-intervention.</td>
<td>EG improved significantly more than the CG group on gait velocity (p=0.003), cadence (p=0.002), step length (p=0.004), BBS score (p=0.048), and ABC score (p=0.017). The double limb support period was significantly lower in the EG compared to the CG (p=0.043).</td>
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<tr>
<td>Author, Year</td>
<td>Study Design (PEDro)</td>
<td>Intervention</td>
<td>Outcomes</td>
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<td><strong>Lokomat</strong></td>
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<tr>
<td>Husemann et al. (2007)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=7 TPS=Acute N=30</td>
<td>30 acute hemiplegic stroke patients were randomized to receive either conventional physical therapy (n=14) or conventional therapy + treadmill training with the Lokomat robotic device (n=16). Both groups received 20 treatment sessions over 4 weeks plus an additional 20 sessions of conventional therapy. Primary outcome measures, assessed between weeks 4 and 5 included the Functional Ambulation Categories (FAC) and the 10-m timed walk test. In terms of FAC, patients in both groups improved over the four-week treatment period from a median score of 0 at baseline to 1 at the end of treatment, but there was no statistically significant difference between groups. Similarly, at the end of treatment, patients in both groups had achieved a walking speed of 0.20 m/s.</td>
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<td>Mayr et al. (2007)</td>
<td>Austria</td>
<td>RCT</td>
<td>PEDro=5 TPS=mean=3mo N=16</td>
<td>16 patients unable to walk an average of 3 months following stroke received 9 weeks of both conventional physical therapy and treadmill training with the Lokomat device. The order of treatment was assigned randomly. Group 1 received 3-weeks of Lokomat training followed by 3-weeks of conventional therapy followed by 3-weeks of Lokomat training. Group 2 patients began with 3 weeks of conventional training. Outcomes were assessed at baseline, and after 3, 6 and 9 weeks and included: modified EU-Walking Scale, Rivermead Motor Assessment (RMA), 10-m timed walk test, 6 min timed walk test, Medical Research Council Scale (MRC), Motricity Index (MI) and Ashworth Scale. Group 1: There were significant improvements in Lokomat group compared with conventional training for the outcomes of EU-walking scale, RMA, MRC and 6-min walk test in both comparisons (i.e. phase 1 vs. phase 2 and phase 2 vs. phase 3). Group 2: There were significant improvements in Lokomat group compared with conventional training during phase 2 for the outcomes of EU-walking scale, MRC, Ashworth Scale and 6-min walk test.</td>
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<tr>
<td>Hornby et al. (2008)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5 TPS=Chronic N=48</td>
<td>48 ambulatory chronic stroke survivors were randomized to 2 groups of locomotor treadmill training. Both groups received 12 training sessions for 30 minutes at similar speeds, with guided symmetrical locomotor assistance using a robotic orthosis versus manual facilitation from a single therapist using an assist-as-needed paradigm. The primary outcome was gait speed; self-selected velocity (SSV) and fast velocity (FV) and was assessed before and after treatment and at 6 months post training. At the end of follow-up both measures of gait speed had improved more in the therapist assist group. SSV: +0.09 vs. 0.05 m/s, p&lt;0.03; FV: .12 vs. 0.07; p&lt;0.02.</td>
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<tr>
<td>Hidler et al. (2009)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5 TPS&lt;6mo N=63</td>
<td>63 participants &lt;6 months post stroke with an initial walking speed between 0.1 to 0.6 m/s were randomized to receive a training program of either Lokomat or conventional gait training. Training for both groups was conducted for 1.5 hrs/week, 3 days/week, for 8-10 weeks to a maximum of 24 sessions. Outcome measures were before and after training. Participants who received conventional gait training experienced significantly greater gains in walking speed and distance compared with those trained on the Lokomat. These differences were maintained at the 3-month follow-up evaluation. There were no significant between group differences on any of the secondary outcome measures.</td>
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9. Mobility and the Lower Extremity

<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>Participants</th>
<th>Intervention</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schwartz et al. (2009)</td>
<td>Israel</td>
<td>RCT</td>
<td>6</td>
<td>TPS&lt;3mo</td>
<td>N=67</td>
<td>67 patients admitted for rehabilitation, within 3 months of stroke, were randomized to 2 groups. Patients in both groups received physical therapy for 30 min/day x 5 days/week x 6 weeks. The experimental group received additional therapy (20 min x 3x/week x 6 weeks) using the Lokomat training device. The control group received an equivalent amount of physical therapy. The primary outcome, assessed before and after treatment, was the ability to walk independently, as assessed by use of the Functional Ambulatory Capacity scale (i.e. FAC score of 4 or 5). Secondary outcomes included the NIHSS, the stroke activity scale (SAS), gait velocity, endurance, and number of climbed stairs.</td>
<td>At the end of 6 weeks, a greater proportion of subjects in the experimental group could walk independently (20/37 vs. 8/28, P&lt;0.03). Subjects in experimental group also had better NIHSS scores at the end of treatment (6.6 vs. 8.0, p&lt;0.01). Among those who achieved independent walking, there were nonsignificant differences between groups on SAS scores and timed walk tests.</td>
</tr>
<tr>
<td>Westlake &amp; Patten (2009)</td>
<td>USA</td>
<td>RCT</td>
<td>6</td>
<td>TPS&gt;6mo</td>
<td>N=16</td>
<td>16 chronic (&gt;6 months) stroke patients were randomly allocated to receive a program of either Lokomat training (n = 8) or manual BWSTT (n = 8) 3x/wk for 4 weeks. Groups were also stratified by fast (mean 0.92 +/- 0.15 m/s) or slow (0.58 +/- 0.12 m/s) training speeds. The primary outcomes, assessed before and after treatment, were self-selected overground walking speed and paretic step length ratio. Secondary outcomes included: fast overground walking speed, 6-minute walk test, and a battery of clinical measures.</td>
<td>There were no significant differences in primary outcomes between the groups at the end of treatment. However, within the Lokomat group, self-selected walk speed, paretic step length ratio, and four of the six secondary measures improved (effect sizes = 0.19-0.60). Within the manual group, only balance scores improved (effect size = 0.57). Group differences between fast and slow training groups were not significant (p&gt;0.28).</td>
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<tr>
<td>Chang et al. (2012)</td>
<td>Republic of Korea</td>
<td>RCT</td>
<td>7</td>
<td>TPS&lt;1mo</td>
<td>N=48</td>
<td>48 persons within 1 month of a stroke were randomized to receive (a) 40 minute robot-assisted gait training using the Lokomat + 60 minutes of conventional PT (NDT approach), 5 days a week for 2 weeks or (b) 60 minutes of conventional PT + additional 40 minutes of conventional PT for the same time period. Cardiopulmonary fitness was assessed in 3 categories: aerobic fitness – peak VO2 and respiratory exchange ratio at peak exercise; cardiovascular response – oxygen pulse, peak heart rate, blood pressure and perceived rate of exertion; ventilator response- minute ventilation and peak exercise and ventilatory</td>
<td>Significant between group differences favoring the robot-assisted gait training group were seen at post-training assessments for aerobic capacity as measured by peak VO2 (p=0.025). No between group differences were observed for cardiovascular or ventilatory response. Significant between group differences favoring the robot-assisted gait training group was also observed for motor function assessed by the lower extremity score of the FMA. There were no significant between group differences for post-training scores on the MI or FAC.</td>
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efficiency. Motor function was assessed by the lower extremity scores of Fugl-Meyer Assessment (FMA), Motricity Index (MI) and Functional Ambulation Categories (FAC).

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N_Start</th>
<th>N_End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Kelley et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=1.44yr</td>
<td>N_Start=21</td>
<td>N_End=20</td>
<td>Lokomat (N=11): Mean Age=66.91yr; Gender: Males=7, Females=4. OGT group received gait training with the body weight support treadmill system.</td>
<td>Patients received 1hr of gait training for 5d/wk for 8wks.</td>
<td>Activities of daily living (ADL); 10-meter walking test (10MWT); 6min walk distance test (6MWD); Fugl-Meyer Lower Extremity Motor Score (FM-LE); Functional Independence Measure locomotion (FIM-L); Barthel Index (BI); Stroke Impact Scale (SIS).</td>
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<tr>
<td>Krewer et al. (2013)</td>
<td>Germany</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS=7.2mo</td>
<td>N_Start=25</td>
<td>N_End=24</td>
<td>Patients with Pusher Behavior (PB) (N=14): Mean age=68±8yr; Gender: Males=11, Females=3. Control patients (N=10): Mean age=63±11yr; Gender: Males=6, Females=4.</td>
<td>Participant with pusher behavior (PB) and those without PB were allocated to three interventions ((1) galvanic vestibular stimulation (GS), (2) driven-gait orthosis (DGO) Lokomat, (3) physiotherapy with visual feedback components (PT-vf)) in a pseudo-random order over the course of one week.</td>
<td>Scale for Contraversive Pushing (SCP); Burke Lateropulsion Scale (BLS).</td>
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<tr>
<td>Ucar et al. (2014)</td>
<td>Turkey</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS=12mo</td>
<td>N_Start=22</td>
<td>N_End=22</td>
<td>Experimental Group (EG; N=11): Mean age=56.2yr. Control Group (CG; N=11): Mean age=61.5yr.</td>
<td>Participants were randomly allocated either to the Lokomat group and underwent active robotic training for 10 sessions (5 sessions per week for 2 weeks), or to the CG and received conventional exercise for the same duration as the Lokomat group. Assessments were conducted at baseline, after the treatment, and at 8 weeks follow-up.</td>
<td>The 10MWT was significantly lower after intervention period, specifically at 8 weeks for the EG (p=0.003, p=0.001), and immediately after the intervention for the CG (p=0.004). The improvement in the 10MWT was significantly different between the two groups immediately after intervention (p=0.007), and after 8 weeks (p&lt;0.001). The TUG was significantly lower immediately after intervention and at 8 weeks for EG (p=0.001, p&lt;0.001), but only immediately after intervention for the CG(p=0.001).</td>
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<tr>
<td><strong>Outcomes</strong></td>
<td><strong>Population</strong></td>
<td><strong>Intervention</strong></td>
<td><strong>Results</strong></td>
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<td>Outcomes: Timed Up-and-Go test (TUG); 10-metre Walking Test (10MWT).</td>
<td>Group 1 (G1, N=3): Mean age=55.3±11.9yr. Group 2 (G2; N=7): Mean age=55.4±15.3yr. Gender: unspecified.</td>
<td>G1 received robot-assisted gait training with the Lokomat for 4wk, and then conventional therapy for 4wk. G2 received the same training but in the reverse order. Robot-assisted gait training was conducted for 30min, 3x/wk for 4wk. Outcomes were evaluated at baseline and post-intervention.</td>
<td>1. There was a significant difference in the MBI transfer subscale between the Lokomat training and the conventional therapy. 2. There were no significant differences in the BBS, MFRT, FAC, MAS, FMA, or MI.</td>
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<td>van Nunen et al. (2015) Netherlands RCT PEDro=4 TPSr=61.6±28.7d TPSc=67.1±49.1d NStart=30 NEnd=Unspecified, but indicates participant drop out.</td>
<td>The EG received a robot-assisted treadmill training that was administered by Lokomat twice a week, combined with conventional overground therapy, 3 times, for 30 mins per week. The Lokomat therapy is a robot-assisted treadmill training. The CG received conventional assisted therapy only, for 3.5 hours per week. This was part of normal rehabilitation. All outcome measures were assessed before and after intervention, at weeks 24 and 36. Outcomes: 10-m timed walk test; Berg Balance Scale (BBS); Motricity index (MI); Brunnstrom –Fugl-Meyer (FM); Rivermead Mobility Index (RMI)(m/s).</td>
<td>1. For walking speed, patients in both groups had higher walking speeds at all follow-up time points compared to baseline. 2. For all secondary outcome measures, there were improvements found for walking and mobility tests, and in the strength of paretic knee extensors relative to baseline at all assessments. 3. There were no statistically significant differences in improvements for walking speed between the intervention groups at 10 weeks or at 24 and 36 weeks after the start of the intervention. The effect size for these changes were small (range: 0.11 to 0.25, from baseline to week 10 respectively). 4. For all secondary outcome measures, and both groups demonstrated statistically significant changes relative to baseline at all assessments (at weeks 10, 24, and 35, respectively). 5. There were no statistically significant differences between the two groups in any of the secondary outcome measures. 6. Overall the study did not find that the Lokomat therapy is superior to, or elicits greater gains than conventional overground therapy.</td>
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<td>Han et al. (2016) Korea RCT PEDro=5 TPSr=21.56±7.98d TPSc=18.10±9.78d NStart=60</td>
<td>The EG received 30min of robot-assisted gait therapy and 30min of</td>
<td>1. There were no significant differences between the EG and CG in the MBI, BBS, FAC, or FMA-LE. 2. Both groups showed significant improvement in the MBI, BBS, FAC, and FMA-LE over time (p&lt;0.001).</td>
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<tr>
<td>NEnd=56</td>
<td>conventional rehabilitation therapy. The CG received 60min of rehabilitation therapy. The intervention was given 5x/wk for 4wk. Outcomes were evaluated at baseline and post-intervention. <strong>Outcomes:</strong> Modified Barthel Index (MBI); Berg Balance Scale (BBS); Functional Ambulation Category (FAC); Fugl-Meyer Assessment for the lower extremity (FMA-LE).</td>
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<td><strong>Other Systems</strong></td>
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<tr>
<td><strong>Freivogel et al.</strong> (2009)</td>
<td>16 non-ambulatory stroke patients with an expected length of hospital stay &gt; 10 weeks participated in a crossover trial examining 2 methods of gait training: 1) 20 treatments of locomotor training with an electromechanical gait device (LokoHelp) followed by 20 treatments of locomotor training with treadmill or 2) task-oriented gait training. Treatments lasted for 30 min, 3-5 x/week for 6 weeks. The primary variable was walking ability (Functional Ambulation Category) assessed after each treatment period. Secondary variables included gait velocity, Motricity-Index, Rivermead-Mobility-Index, number of therapists needed, and discomfort and effort of patients and therapists during training. Patients improved following each of the treatment periods. There were no significant differences between intervention types. However, during intervention with the LokoHelp, significantly fewer therapists were needed, and they reported less discomfort and a lower level of effort during training sessions.</td>
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<tr>
<td>Germany RCT PEDro=8 TPS=Acute N=16</td>
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<td><strong>Fisher et al.</strong> (2011)</td>
<td>20 patients with hemiparesis, within 1 year post stroke were randomized to an intervention group (RAGT), which consisted of 30 minute sessions of goal oriented physiotherapy followed by 30 minutes of Robot-assisted gait training using the Autoambulator, or the control group (CG) which received 1 hour of goal-oriented physiotherapy. 24 sessions were conducted for each group over 6-8 weeks. Outcome measures included the 8 m walk test, 3 minute walk test and Tinnetti Balance Assessment Both groups showed significant improvement from baseline on the 8 m walk test (p=0.0015), 3 minute walk test (p=0.0004) and Tinetti balance assessment (p&lt;0.0001). No significant between group differences were reported.</td>
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<tr>
<td>US RCT PEDro=5 TPS&lt;1yr N=20</td>
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<tr>
<td><strong>Kim et al.</strong> (2015)</td>
<td>Population: Experimental Group (EG, N=13): Mean age=54.1±12.6yr; Gender: Males=9, Females=4. Control Group (CG; N=13): Mean age=50±16.2yr; Gender: Males=10, Females=3. <strong>Intervention:</strong> The EG received robotic therapy using the Walkbot and the CG received conventional therapy. Therapy was done for 40min/d, 5x/wk for 4wk. Outcomes were done at baseline, 4wk, and 8wk. There were significant group by time interactions on the FAC (p=0.02), BBS (p=0.03), and K-MBI (p=0.00). There are no significant interactions between the EG and CG on the EG-5D or MAS.</td>
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<td>Korea RCT PEDro=6 TPS=80.1±60.2d TPS=119.5±84.3d NStart=30 NEnd=26</td>
<td>1.</td>
<td>2.</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro Score</td>
<td>TPS (EG)</td>
<td>TPS (CG)</td>
<td>Start N</td>
<td>End N</td>
<td>Population</td>
<td>Intervention</td>
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<td><strong>Watanabe et al. (2014)</strong></td>
<td>Japan</td>
<td>Case Control</td>
<td>4</td>
<td>58.9d</td>
<td>50.6d</td>
<td>32</td>
<td>22</td>
<td>Experimental Group (EG; N=11): Mean age=67.0±16.8yr; Gender: Males=7, Females=4. Control Group (CG; N=11): Mean age=75.6±13.9yr; Gender: Males=4, Females=7.</td>
<td>Participants were randomly allocated either to the EG and received 20 minute sessions of Hybrid Assistive Limb (HAL) training for 4 weeks, or to the CG and received gait training for 4 weeks.</td>
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<tr>
<td><strong>Ogata et al. (2015)</strong></td>
<td>Japan</td>
<td>Case Control</td>
<td>No Score</td>
<td>Acute</td>
<td>Acute</td>
<td>91</td>
<td>91</td>
<td>Population: Experimental Group (EG, N=14): Mean age=65(57-69)yr; Gender: Males=5, Females=9. Control Group (CG; N=77): Mean age=64(57-75)yr; Gender: Males=43, Females=33.</td>
<td>The EG received hybrid assistive limb rehabilitation for leg function, and the CG received conventional rehabilitation. Outcomes were evaluated at baseline and post-intervention.</td>
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<tr>
<td><strong>Yoshimoto et al. (2015)</strong></td>
<td>Japan</td>
<td>Case Control</td>
<td>No Score</td>
<td>92.4±44.8mo</td>
<td>80.5±48.9mo</td>
<td>18</td>
<td>18</td>
<td>Population: Experimental Group (EG; N=9): Mean age=66.6±8.4yr; Gender: Males=6, Females=3. Control Group (CG; N=9): Mean age=63.7±11.0yr; Gender: Males=7, Females=2.</td>
<td>The EG underwent a high-speed gait training program with an exoskeleton robot hybrid assistive limb (HAL) and the CG underwent conventional gait training. Sessions were 20min/d, 1x/wk for 8wk. Assessments were done at baseline, 4wk and 8wk.</td>
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<tr>
<td><strong>Fukuda et al. (2016)</strong></td>
<td><strong>Population</strong>: Group 1 (G1; N=9): Mean age = 59.4±12.5yr; Gender: Males = 5, Females = 4. Group 2 (G2; N=14): Mean age = 63.2±13.9yr; Gender: Males = 6, Females = 8. <strong>Intervention</strong>: G1 received treatment from multiple different types of hybrid assistive limb (HAL) robots for a mean of 19.4d, while G2 received rehabilitation from a single type of HAL robot for a mean of 14.9d. Outcomes were evaluated at baseline and post-intervention. <strong>Outcomes</strong>: Brunnstrom stage; Barthel Index (BI); Functional Independence Measure (FIM) G1 showed significantly better outcomes in the Brunnstrom stage for upper extremity (p=0.025) and lower extremity (p=0.014), BI (p=0.017) and FIM scores (p=0.033).</td>
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<td><strong>Waldman et al. (2013)</strong></td>
<td>Twenty-four stroke survivors (&gt; 3months post stroke) with reduced ankle range of motion and strength were randomly assigned to a robot group (intervention) or exercise program (control). Subjects in the robot group received 18 sessions (3 times a week for 6 weeks), each session consisting of 60min of active stretching and movement training of the affected ankle. Participants in the control group were given written and verbal instructions on how to perform passive calf stretches and active movement exercises of the impaired ankle. Participants were told to perform the exercises 3 times a week for 6 weeks and to log their performances. Clinical evaluations on movement ability, balance and function included the Modified Ashworth Scale (MAS), Stroke Rehabilitation Assessment of Movement (STREAM), the 6 Minute Walk Test (6MWT). Evaluations were performed pre- and post-training, and at 6-weeks post training (follow-up). From pre- to post-training MAS scores decreases significantly in the robot group (2.9±1.2 to 1.8±1.6, P=0.018). The STREAM evaluation improved significantly after training in the robot group with improvements retained at follow-up. STREAM evaluations were found to have improved at follow-up for the control group. Berg balance scores improved significantly for subjects in the robot group post-training and at follow-up. No improvements were found at any time point for either group regarding the 6MWT.</td>
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<td><strong>Forrester et al. (2014)</strong></td>
<td><strong>Population</strong>: Robot Group (N=18): Mean Age = 63.3yr; Gender: unspecified. Manual Group (N=16): Mean Age = 60.0yr; Gender: unspecified. <strong>Intervention</strong>: All patients received their usual physical therapy according to the inpatient standards of care in addition to intervention. Experimental therapies were provided for 60min/d, 5d/wk with some avg # training sessions of 10.9 robot, 10.3 manual (insignificantly different p=0.620). Robot Training-used dorsi- or plantarflexion of ankle 1. There was a statistically significant increase within but not between groups in gait velocity (18.1cm/s mean increase Robot, 14.8cm/s manual, F=41.82, p&lt;0.001) and ankle range of motion in dorsiflexion range (robot 19.1° increase, 9.8° in manual, F=20.61, p&lt;0.001). 2. There was a statistically significantly greater change in robot group mean paretic to non-paretic step-time ratio after intervention (from 2.33 to 1.44 in robot d=0.75, 1.98 to 1.89 in manual, p=0.032 d=0.03) with a significant group x time interaction (F=4.50, p=0.042).</td>
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with an ankle robot supporting the paretic leg to control movement in videogame. Manual training-paretic ankle was moved manually by therapist in dorsi-plantarflexion and inversion/eversion motions with # of movements matching robot training group. **Outcomes:** Timed floor walks; Berg Balance Scale (BBS), Functional Independence Measure (FIM), robot-measured positional data; manual muscle test; ratio of paretic to non-paretic step times/lengths for interlimb symmetry.

3. **There was a statistically significantly greater increase in non-paretic step length in robot vs manual (mean increase 13.2cm in robot p<0.001, d=0.71 vs 6.2cm manual p=0.015, d=0.50), but a non-significant group time interaction for absolute step length ratios (F=2.53, p=0.12).**

4. **Mean angular velocity showed a statistically significant group x time interaction (p=0.055) with a significant main effect for time (p=0.003). ΔM from 3.7°/s to 8.9°/s after intervention in robot.**

**Stein et al. (2014)**
USA 
RCT 
PEDro=7 
TPSRTG=49.1±38.9mo 
TPSSEG=88.5±153.0mo 
NStart=24 
NEnd=20

**Population:** Robotic Training Group (RTG; N=12): Mean age=57.6±10.7yr; Gender: Males=83%, Females=17%. Exercise Group (EG; N=12): Mean age=56.6±15.1yr; Gender: Males=58%, Females=42%.

**Intervention:** The robotic treatment group received 1 hour of individualized physical therapy with the device, 3d/wk for 6 consecutive weeks (total of 18 sessions). Each 1 hr session included brief rest periods, and goal administering approximately 50 mins of active therapy. The CG received 1 hr of group exercise without the use of the robotic device 3d/wk for 6 consecutive weeks. Assessments were taken at four time points: at study entry, after 6 weeks, after 1 and 3 mo on completion of the training program.

**Outcomes:** 10-m walk test (10MWT); Berg Balance Scale (BBS).

1. **The ITT showed that after 6 weeks of training, there were no statistically significant within-group differences found for the primary outcome measure.**
2. **There was a greater improvement in balance as indicated by the BBS. There were no statistically significant differences between the groups after training.**

**Buesing et al. (2015)**
USA 
RCT 
PEDro=6 
TPSEG=5.4±0.8yr 
TPSCG=7.1±1.5yr 
NStart=54 
NEnd=50

**Population:** Experimental Group (EG, N=25): Mean age=62±3yr; Gender: Males=17, Females=8. Control Group (CG; N=25): Mean age=60±2yr; Gender: Males=16, Females=9.

**Intervention:** EG received training with the Stride Management Assist system for gait training, and the CG received functional task specific training. Each individual underwent fast-velocity walking trails and self-selected speed walking trails. Training occurred for 45min/d, 3x/wk, for 6-8wk for a total of 18 visits. Outcomes were evaluated at baseline (T0), the 10th visit (T1), post-intervention (T2), and also at a 3mo follow-up (T3).

**Outcomes:** Gait velocity; cadence; step time; stance time; swing time; double support time; step length; stride length; spatial asymmetry; temporal asymmetry.

1. **There were no significant differences between the EG and CG on gait velocity, cadence, step time, swing time, double support time, step length, stride length, spatial asymmetry, or temporal asymmetry.**
9.7 Electrical Stimulation

9.7.1 Functional Electrical Stimulation (FES)

Table 9.7.1.1 Summary of Studies Evaluating Functional Electrical Stimulation

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gait Training</strong></td>
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<tr>
<td><strong>Cozean et al.</strong> (1988) USA RCT PEDro=6 TPS=NA N=36</td>
<td>Single blind RCT of 36 patients and 4 therapy groups: Control therapy consisting of standard physical therapy regimen; Electromyography Biofeedback (BFB); Functional electrically stimulation (FES); and Combined therapy with BFB and FES. 30 minutes of treatment three times per week for six weeks.</td>
<td>Combined therapy of BFB and FES showed greater improvement indexes of knee flexion and ankle dorsiflexion compared to control, and either BFB or FES alone. Greatest gains in stride length and gait cycle time seen in the combined therapy group.</td>
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</table>

| Daly et al. (2006) USA RCT PEDro=8 TPS>1yr N=32 | 32 stroke patients (>1 year post stroke) were randomly assigned to 1 of 2 groups: 1) With Functional Neuromuscular Stimulation using intramuscular electrodes (FNS-IM) incorporated into treatment or 2) No FNS (Control). Each group received 1.5 hour sessions 4 times a week for 12 weeks. Therapy included 30 min of body weight supported treadmill training (BWSTT) and 30 min of Overground (OG) walking and 30 min of strengthening and coordination. Evaluations included Tinetti gait (TG), FMLE, Fugl-Meyer knee flexion coordination (FMKnFx), Tinetti balance (TB), six-minute walking test (6MWT). | After 12 weeks of treatment the group receiving FNS-IM produced a significantly larger gain for the primary measure TG compared with the NO-FNS group (p=0.003). The FNS-IM group also made significant gains for FMKnFx versus No-FNS (p=0.049). |

<p>| Kottink et al. (2007) Netherlands RCT PEDro=5 TPS=Chronic N=29 | 29 chronic stroke subjects with hemiplegia and foot drop were randomized to two groups. Subjects in the intervention group received an implantable 2-channel peroneal nerve stimulator for correction of their drop foot. The control group continued using their conventional walking device, consisting of an ankle-foot orthosis, orthopedic shoes, or no device. Primary outcome, walking speed, was assessed at baseline, 4, 8, 12 and 26 weeks, using the six-minute walk test (6MWT) and by using a 10-m walkway. | There was a significantly greater improvement in performance on the 6MWT at week 26, favouring the FES group (p=0.049). Comfortable walking speed measured on a 10-m walkway was also significantly improved in favour of FES (R=.038). |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Location</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
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<tbody>
<tr>
<td>Kojovic et al. (2009)</td>
<td>Denmark</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS=Acute</td>
<td>N=13</td>
</tr>
<tr>
<td>Daly et al. (2011)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS&gt;6mo</td>
<td>N=53</td>
</tr>
<tr>
<td>Morone et al. (2012)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS=Subacute</td>
<td>N=20</td>
</tr>
<tr>
<td>Park &amp; Kang (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>PEDro=4</td>
<td>TPS=NA</td>
<td>NStart=20, NEnd=20</td>
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</table>

**Kojovic et al. (2009)**
13 acute stroke subjects with hemiplegia received a standard inpatient rehabilitation program. During walking sessions, which lasted for 45 min, 5x/week x 4 weeks, 7 subjects were randomized to receive functional electrical stimulation during walking with a four channel stimulator targeting 4 muscle groups (quadriceps, hamstrings, soleus and tibialis anterior) to augment both knee and ankle flexion/extension. The control group did not receive FES. Outcome measures, assessed before and after treatment included Fugl-Meyer (FM) scores, BI, walking velocity and Physiological Cost Index (PCI).

Over the study period there were statistically significant improvements in the average scores for all outcome measure among patients in the FES group, but not the control group. There were significant differences in the changes of FM, BI, walking velocity and PCI which occurred during the 4 weeks of treatment between the FET and CON groups.

**Daly et al. (2011)**
53 patients with stroke onset of > 6 months received a 12 week treatment program (1.5 hrs, 4 x per week) consisting of strengthening exercises, overground gait training and body-weight supported treadmill training. Patients were randomized to intramuscular FES (electrodes were implanted into 8 muscles)(n=59) or no FES (n=66). The primary outcome measure was the Gait Assessment and Intervention Tool (GAIT) assessed at baseline, post treatment and at 6 months.

Patients in both groups improved over the treatment period. Patients in the IM FES group achieved significantly greater improvement in GAIT (p=0.045) following treatment that were maintained at 6 months. 50% of patients in the IM FES group improved by at least 10 points on the GAIT compared with only 21% of patients in the control group.

**Morone et al. (2012)**
20 individuals in the subacute phase of stroke were randomized to receive FES WalkAide plus conventional physiotherapy or conventional physiotherapy only. All individuals received 20, 40-minute sessions over 4 weeks. Outcomes including the 10-m walk test (10-m), Functional Ambulation Classification (FAC), Barthel Index (BI), Rivermead Mobility Index (RBI), and Medical Research Council (MRC) were assessed immediately post treatment and at 1 month follow-up.

Both groups significantly improved on all outcome measured immediately post treatment (p<0.05). Between-group analysis demonstrated greater improvements for the active group on 10-m (p=0.021) and FAC (p=0.023), but not BI (p=0.114) or RMI (p=0.057).

**Park & Kang (2013)**
Population: Experimental group (EG; N=10): Age range=30-79yr; Gender: Males=6, Females=4. Control group (CG; N=10): Age range=30-79yr; Gender: Males=5, Females=5.

**Intervention**: Participants were randomly allocated to either EG and received functional electrical stimulation (FES) and were asked to watch a 15-minute video on gait, or to the CG and received FES without watching a training video. The treatment lasted 6 weeks. Participants were assessed before the intervention and after the intervention period.

**Outcomes**: Weight distribution WD (anterior-
posterior (AP), right-left (RL)); stability index (SI); Gait velocity (GV).

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS Range</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheffler et al. (2013b)</td>
<td>USA</td>
<td>RCT</td>
<td>7</td>
<td>44.7mo</td>
<td>110</td>
<td>84</td>
<td>Peroneal nerve stimulation (PNS; N=54): Mean age=52.8±12.2yr; Gender: Males=30, Females=24. Usual care group (UC; N=56): Mean age=53.2±10.2yr; Gender: Males=37, Females=9.</td>
<td>Participants were randomly allocated either to the peroneal nerve stimulation (PNS) group or to the usual care group. The subjects were treated for 12 weeks and followed up for 6 mo. Assessments were collected at baseline (t1), end of the device usage period (t2), and at 12 weeks (t3), and at 24 weeks (t4) posttreatment. Lower limb portion of the Fugl-Meyer (FM) assessment; modified Emory Functional Ambulation profile (mEFAP); stroke specific quality of life (SSQOL).</td>
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<td>1. There was no significant difference between the two groups on the FM raw scores. Additionally, no significant interaction between the group and time effect was found. 2. The time effect for the FM scores was found to be significant (p&lt;0.007) however, no significant changes in the FM score trajectories of the two groups from baseline to each time point were found. 3. The mEFAP did not differ significantly between the two groups, and no significant interaction between the groups and the time effect was found. 4. The effect of time was found to be significant (p&lt;0.001), where the mEFAP scores were lower at t2, t3, and t4 than the baseline values (t1). 5. There was no significant effect of group allocation or an interaction between group and time effect regarding the SSQOL. 6. Both groups demonstrate the same trajectory of a positive average change in SSQOL during treatment, which level off during posttreatment period.</td>
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<tr>
<td>Spaich et al. (2014)</td>
<td>Denmark</td>
<td>RCT</td>
<td>8</td>
<td>14-62d</td>
<td>30</td>
<td>28</td>
<td>Age range=36-83yr; Gender=Not reported.</td>
<td>Patients were randomized to receive gait training alone or with functional electrical stimulation (FES) for the nociceptive withdrawal reflex. Training was delivered 30min/d for a total of 20 sessions. Functional Ambulation Category (FAC); Gait kinetics; Gait kinematics.</td>
<td></td>
<td>1. FAC significantly improved in both groups after treatment, but was not significantly different between groups (p=0.09). 2. Comfortable and fastest walking velocity improved in both groups after treatment, and the improvement was significantly greater in the FES group (p&lt;0.001). 3. Stance symmetry ratio significantly improved in both groups after treatment, and was significantly lower in the FES group (p&lt;0.02). 4. Gait cycle was significantly shorter in the FES group, regardless of FAC (p&lt;0.001). 5. Stance phase was significantly longer in the FES group, only in patients with FAC=3 (p&lt;0.001).</td>
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<tr>
<td>Tan et al. (2014)</td>
<td>China</td>
<td>RCT</td>
<td>7</td>
<td>41.3d</td>
<td>55</td>
<td>37</td>
<td>Four-channel Group (4C; N=16): Mean age=63.4±10.6yr; Gender: Males=8, Females=8. Dual-channel Group (2C; N=14): Mean age=64.6±8.3yr; Gender: Males=8, Females=6. Placebo Group (N=15): Mean age=67.0±9.0yr; Gender: Males=8, Females=9.</td>
<td>Participants were randomly assigned to either the four-channel group</td>
<td></td>
<td>1. After 3 weeks of treatment, there was a significant difference in FMA scores between the 4C and the 2C groups (p=0.024), but no significant difference between the 4C and the placebo groups. 2. There was no significant difference in PASS and BBS scores among the 3 groups after 3 weeks of treatment. However, the difference between the 4C and the placebo groups in</td>
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(4C) and received four-channel functional electrical stimulation (FES) therapy applied to the affected lower extremity to mimic a normal gait cycle, or to a dual-channel group and received dual-channel FES therapy activating the affected plantar flexor, or to the placebo group and received placebo 4C FES therapy. Stimulation lasted 30 minutes per sessions, 1 session per day, 5 days a week, for 3 weeks. All subjects received the same conventional stroke rehabilitation program for 30 minutes per day, for 5 days a week, for 3 weeks. Participants were assessed at baseline, during the 3 weeks of treatment, and at 3-month follow-up after the end of the treatment period.

**Outcomes:** Modified Barthel Index (MBI); Functional ambulatory category (FAC); Postural assessment scale for Stroke patients (PASS); Berg balance scale (BBS); lower extremity Fugl-Meyer Movement Assessment (FMA).

### Sheffler et al. (2015)

**USA**  
RCT  
PEDro=6  
TPS>12wk  
N\textsubscript{Start}=110  
N\textsubscript{End}=110  

**Population:** Experimental Group (EG, N=54). Control Group (CG; N=56): Age>18yr; Gender: unspecified.

**Intervention:** The EG received surface peroneal nerve stimulation, and the CG received usual care, 48 of which also received an ankle foot orthosis. Training was 1h, 5x/wk for 12wk. Outcomes were assessed at baseline, post-intervention, and 6mo.

**Outcomes:** Cadence; steps per minute; double support; stride length; walking speed; peak hip flexion during swing, peak knee flex during swing; peak ankle dorsiflexion during swing; ankle dorsiflexion at initial contact; peak ankle abduction during swing; peak ankle external rotation during swing; anterior-posterior ground reaction force; peak hip power pre-swing; peak ankle power at push-off.

1. There were no significant group by time effects on any of the outcomes.
2. There was a time effect on cadence (p=0.012), stride length (p<0.001), walking speed (p<0.001), peak ankle dorsiflexion during swing (p=0.031), anterior-posterior ground reaction force (p=0.004), peak hip power pre-swing (p<0.001) and at push off (p=0.005).

### Cycling

**Janssen et al. (2008)**  
UK  
RCT  
PEDro=6  
TPS>5mo  
N=12  

12 stroke patients more than 5 months post stroke, with lower-extremity hemiparesis were randomly assigned to groups that performed cycling exercise, one with electrical stimulation (ES) evoking muscle contractions and a control group with ES not evoking muscle contractions. Subjects trained twice a week for 6 weeks. Outcome measures included: changes in aerobic capacity and maximal power output, functional.

There were significant within group improvements in the outcomes of aerobic capacity, maximal power output, BBS, and the 6MWT. There were no significant between group differences on any of the outcomes assessed.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Type</th>
<th>PEDro</th>
<th>TPS</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambrosini et al. (2011)</td>
<td>Italy</td>
<td>RCT</td>
<td>8</td>
<td>6mo</td>
<td>35</td>
<td>35</td>
<td>35 patients who were able to sit for 30 minutes and were within 6 months of stroke were randomized to receive FES-induced cycling training or placebo FES cycling for 4 weeks (20 sessions, 25 minutes each). Primary outcome measures included the leg subscale of the Motricity Index (MI) and gait speed during a 50-meter walking test. Participants were evaluated before training, after training, and at 3- to 5-month follow-up visits.</td>
<td>At follow-up, patients in both groups had achieved significant gains in MI and gait speed (p&lt;0.01). After controlling for difference in baseline MI scores, patients in the FES group gained significantly more MI points at the end of treatment (30 vs. 11, p=0.002) and at follow-up (39 vs. 10, p=0.001). Patients in the FES group also fared better on the Trunk Control Test and the Upright Motor Control test at both the end of treatment and follow-up.</td>
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</tbody>
</table>
| Bauer et al. (2015)                  | Austria       | RCT    | 7     | 62±43d | 40 (19) | 37 (18) | Population: Experimental Group (EG; N=19): Mean age=59±14yr; Gender: Males=12, Females=7. Control Group (CG; N=18): Mean age=64±11yr; Gender: Males=9, Females=9. | Intervention: Participants were randomized to receive Functional Electrical Stimulation (FES) during cycling (EG group) or cycling with no FES (CG group). Both groups cycled for 20min, 3x/wk for 4wk, for a total of 12 sessions. Outcomes were assessed at baseline, 4wk, and 6wk. | 1. There was a significantly greater improvement in FAC in the EG group compared to the CG group from baseline to 4wk (p=0.013) but not baseline to 6wk (p=0.148).  
2. There was a significantly greater improvement in POMA in the EG group compared to the CG group from baseline to 4wk (p<0.0004) but not baseline to 6wk (p=0.069).  
3. There was no significant difference between groups in MI from baseline to 4wk (p=0.651) and baseline to 6wk (p=0.663).  
4. There was no significant difference between groups in MAS scores. |  |
| De Sousa et al. (2016)               | Australia     | RCT    | 7     | 34 (22-49) | 40 (19) | 38 (20) | Population: Experimental Group (EG; N=19): Mean age=62±15yr; Gender: Males=14, Females=6. Control Group (CG; N=20): Mean age=60±16yr; Gender: Males=13, Females=7. | Intervention: EG received an individualized functional electrical stimulation (FES) cycling program 5x/wk for 4wk. FES was applied to the knee extensors, knee flexors, ankle dorsiflexors and plantar flexors. EG also received physiotherapy 1hr/d for 4 wk. CG received physiotherapy 1hr/d for 4wk. Assessments were conducted at baseline (T0) and 4wk (T1). | 1. FIM-BC, FIM-W, FIM-S did not produce significant differences between EG and CG at T1.  
2. TS and SKM of the unaffected lower limb observed no significant differences between EG and CG at T1.  
3. SKM of the affected limb observed significant improved in EG compared to CG at T1 (p<0.05). |  |
| Peri et al. (2016)                   | Italy         | RCT    | 7     | 14.4±2.7d | 14 (8) | 16 (8) | Population: Experimental Group (EG; N=8): Mean age=71.8±12.9yr; Gender: Males=2, Females=6. Control Group (CG; N=8): Mean age=76.4±8.7yr; Gender: Males=7, Females=1. | Intervention: The EG underwent FES-augmented cycling training combined with 6MWT, Berg Balance Scale (BBS), Rivermead Mobility Index (RMI) and lower-limb muscle strength. | 1. There was a significant time effect on 6MWT (p=0.000), FIM (p=0.000), gait velocity (p=0.000), double support time (p=0.002), Wp (p=0.0004), and EI (p=0.044).  
2. There was a group effect on EI (p=0.045) favouring the EG. |  |
9. Mobility and the Lower Extremity

**Treadmill**

**Cho et al.** (2015)
Korea
RCT
PEDro=6
TPS<sub>EG1</sub>=22.5±12.6mo
TPS<sub>EG2</sub>=22.5±14.1mo
TPS<sub>CG</sub>=21.6±6.7mo
N<sub>Start</sub>=36
N<sub>End</sub>=31

**Population:** Experimental Group 1 (EG1, N=10): Mean age=57.0±9.1yr; Gender: Males=7, Females=3. Experimental Group 2 (EG2, N=10): Mean age=53.3±9.2yr; Gender: Males=7, Females=3. Control Group (CG; N=11): Mean age=57.8±7.9yr; Gender: Males=6, Females=5.

**Intervention:** EG1 received treadmill training with FES applied to the gluteus medius and tibialis anterior muscles, EG2 received treadmill training with FES applied to the tibialis anterior, and the CG received treadmill training. Training was 30min, 5x/wk for 4wk. Participants also received regular physical therapy for 1h/d, 5x/wk for 4wk. Outcomes were evaluated at baseline and post-intervention.

**Outcomes:** Medical Research Council scale (MRC); 6 Minute Walk Test (6MWT); Berg Balance Scale (BBS); gait velocity; cadence; stride length; double support time; single support time; temporal asymmetry; spatial asymmetry.

There were significant differences between EG1, EG2 and the CG on gait velocity (p=0.001), cadence (p=0.001), single support time (p=0.033), temporal asymmetry (p=0.050), BBS (p=0.027), and the 6MWT (p=0.030).

**Hwang et al.** (2015)
Korea
RCT
PEDro=7
TPS<sub>EG</sub>=192.53±18.79d
TPS<sub>CG</sub>=194.07±18.95d
N<sub>Start</sub>=32
N<sub>End</sub>=30

**Population:** Experimental Group (EG, N=15): Mean age=50.00±7.55yr; Gender: Males=9, Females=6. Control Group (CG; N=15): Mean age=49.47±5.01yr; Gender: Males=8, Females=7.

**Intervention:** The EG received treadmill training with tilt sensor FES and the CG received treadmill training with placebo tilt sensor FES. Training was 30min/d for 4wk. Outcomes were analyzed at baseline, post-intervention, and a follow-up at 4wk.

**Outcomes:** Timed Up and Go test (TUG); Berg Balance Scale (BBS); 10 Metre Walk Test (10MWT).

1. There were significant improvements in the TUG (p<0.001), BBS (p<0.001), and 10MWT (p<0.001) in both the EG and CG from baseline to post-intervention.
2. The EG improved significantly compared to the CG on the TUG, BBS, and 10MWT (p<0.001, p<0.01, p<0.05 respectively) at follow-up.

**Awad et al.** (2016)
USA
RCT
PEDro=6
TPS<sub>EG1</sub>=2.68±2.27yr

**Population:** Experimental Group 1 (EG1, N=15): Mean age=63.25±5.40yr; Gender: Males=11, Females=4. Experimental Group 2 (EG2, N=16): Mean age=55.30±5.80yr; Gender: Males=9, Females=7. Control Group

There were no significant differences between the groups on the 6MWT for any time interval.

**Voluntary pedaling,** and the CG had standard physiotherapy. Participants received 75min of training, 5x/wk for 3wk. Assessments were done baseline and post-intervention.

**Outcomes:** 6 Minute Walking Test (6MWT); Function Independence Measure (FIM); gait speed; double support time; work produced by the paretic leg (Wp); mechanical efficiency index (EI)
<table>
<thead>
<tr>
<th>Study</th>
<th>Location</th>
<th>Design</th>
<th>PEDro Score</th>
<th>Study Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MacDonell et al. (1994)</strong></td>
<td>Australia</td>
<td>RCT</td>
<td>5</td>
<td>TPS = 25d; N = 38</td>
<td>38 patients randomized to receive cyclical electrical stimulation (CES) 5 days or functional activities 3 days a week for 20 min sessions with an exercise and physical therapy program for 4 weeks (FES group) or to receive self-exercise program two to three times per day for 15 min sessions independently with an exercise and physical therapy program performed in the same manner as the FES group for 4 weeks (NFES group).</td>
<td>Those treated with FES had a greater rate of improvement in Massachusetts General Hospital Functional Ambulation Classification scores.</td>
</tr>
<tr>
<td><strong>Bogataj et al. (1995)</strong></td>
<td>Slovenia</td>
<td>RCT</td>
<td>6</td>
<td>TPS=NA; N=20</td>
<td>20 patients with severe hemiplegia secondary to CVA were assigned to receive either multi-channel functional electrical stimulation therapy (MFES) combined with standard therapy or to receive standard therapy alone. Treatment was crossed-over. Patients were in good cardiovascular health such that extended therapy did not pose a health risk and they were able to stand independently or with the aid of a therapist. Their perceptual and intellectual abilities were preserved and demonstrated sufficient functional response.</td>
<td>Therapies resulted in significantly different outcomes in Fugl-Meyer, ground reaction force, gait speed, stride length and gait cadence and TCP. MFES combined with therapy in the first period was more effective than in second period or conventional therapy during the first or second period.</td>
</tr>
<tr>
<td><strong>Newsam &amp; Baker (2004)</strong></td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>TPS=Acute; N=20</td>
<td>20 acute stroke patients admitted for rehabilitation were randomized to receive standard therapy + an electrical stimulation facilitation program, 5 days a week for 3 weeks or to standard therapy alone. Electrodes were placed over the motor points of the vastus lateralis and the vastus medialis oblique. Stimulation intensity was targeted at the minimal amplitude necessary to provide control of the knee extension during weight-bearing activity. Outcomes included maximal voluntary isometric torque (MVIT) and motor unit recruitment.</td>
<td>MVIT increased by 77% in patients receiving electric stimulation, compared with a 31% increase for the control group although there was not a statistically significant difference between groups. Motor unit recruitment increased from 35% to 53% for the study group, whereas the control group recorded no change in recruitment ability.</td>
</tr>
<tr>
<td><strong>Yan et al. (2005)</strong></td>
<td>China</td>
<td></td>
<td></td>
<td>46 acute stroke patients randomized to 1 of 3 groups receiving standard rehabilitation with</td>
<td>After 3 weeks of treatment, there was a significant reduction in the percentage of</td>
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<tr>
<td>Reference</td>
<td>Location</td>
<td>Study Design</td>
<td>PEDro Score</td>
<td>TPS Duration</td>
<td>N Start</td>
<td>N End</td>
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<tr>
<td>Cheng et al. (2010)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>6</td>
<td>Acute</td>
<td>46</td>
<td></td>
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<tr>
<td>You et al. (2014)</td>
<td>China</td>
<td>RCT</td>
<td>7</td>
<td>&gt;3 mo</td>
<td>42</td>
<td>37</td>
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<td>Study</td>
<td>Country</td>
<td>Study Type</td>
<td>PEDro Score</td>
<td>TPS Group</td>
<td>TPS Control</td>
<td>Start</td>
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<tr>
<td>Gurcan et al. (2015)</td>
<td>Turkey</td>
<td>RCT</td>
<td>6</td>
<td>TPS &lt;sub&gt;FES&lt;/sub&gt; = 10.89±16.85mo</td>
<td>TPS &lt;sub&gt;CG&lt;/sub&gt; = 17.69±20.96mo</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt; = 32</td>
</tr>
<tr>
<td>Shendkar et al. (2015)</td>
<td>India</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS &lt;sub&gt;FES&lt;/sub&gt; = 5.5mo</td>
<td>TPS &lt;sub&gt;CG&lt;/sub&gt; = 5.2mo</td>
<td>N&lt;sub&gt;Start&lt;/sub&gt; = 34</td>
</tr>
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</table>

**Population:**
- **Gurcan et al. (2015):**
  - Experimental Group (EG; N=19): Mean age=57.42±12.51yr; Gender: Males=14, Females=5. Control Group (CG; N=13): Mean age=58.38±12.59yr; Gender: Males=4, Females=9.
- **Shendkar et al. (2015):**
  - Functional Electrical Stimulation Group (FES; N=14): Mean age=51.0±11.0yr; Gender: Males=9, Females=5. Control Group (CG; N=4): Mean age=48.7±12.7yr; Gender: Males=9, Females=5.

**Intervention:**
- **Gurcan et al. (2015):** EG received electrical stimulation (ES) 20min/d 5x/wk for 3wk in addition to conventional treatment. CG received conventional treatment methods for 3wk. Assessments were conducted at baseline (T0) and post-treatment (T1).
- **Shendkar et al. (2015):** Participants were divided into two equal groups, where one group received functional electrical stimulation (FES) on the lower affected limb for 30 minutes, and the other group received conventional physiotherapy for 60 minutes. Participants were assessed before the intervention and after the intervention. [no additional information provided]

**Outcome:**
- **Gurcan et al. (2015):**
  - Brunnstrom Motor Staging (BMS); Modified Ashworth Scale (MAS); Functional Ambulation Scale (FAS); Clonus Score (CS); Dorsiflexion Strength of Ankle (DSA); Range Of Motion (ROM); Functional Independence Measure (FIM); 10 Meter Walking Test (10MWT).
- **Shendkar et al. (2015):**
  - Walking Speed; Cadence; Step Length; Single Limb Support (SLS); Double Limb Support (DLS); Pulling Power; Swing Power; Ground Impact; stride Length; Temporal EEG properties (wide band amplitude, beta 3 mean, beta 4 mean, beta 5 mean); EEG Spectral Properties (alpha peak frequency); sEMG Temporal Properties (sEMG RMSS value, sEMG peak value, average slope); sEMG spectral properties (mean power frequency, median power frequency, spectral edge frequency).

**Results:**
- **Gurcan et al. (2015):** Both groups improved significantly (p<0.05) on the MBI. The total MBI scores in the FES group increased greater than the CG (p<0.05).
- **Shendkar et al. (2015):** Both FES and CGs demonstrated a significant change from baseline to posttreatment on the SLS (p=0.020), SLS/DLS ratio (p=0.020), pulling acceleration (p=0.015), swing power (p=0.020), and ground impact (p=0.020).
7. Significant group X time interaction was found regarding the sEMG RMS value (p=0.028), mean power frequency (p=0.10), and median power frequency (p=0.014).
8. The FES group differed significantly from the CG on the sEMG RMS value (p=0.033), mean power frequency (p=0.024), and median power frequency (p=0.021).

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>TPS</th>
<th>N</th>
<th>Overview</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peurala et al. (2005)</td>
<td>USA</td>
<td>RCT</td>
<td>6</td>
<td>Chronic</td>
<td>45</td>
<td>45 ambulatory chronic stroke subjects were randomized to 3 groups: 1) gait trainer (with BWS) exercise with functional electric stimulation (GTstim), 2) gait trainer (with BWS) exercise without stimulation (GT), and 3) walking overground (WALK). All patients practiced gait for 15 sessions during 3 weeks (each session, 20 min), and received additional physiotherapy 55 minutes daily. Outcome measures included: ten-meter walk test (10MWT), six-minute walk test (6MWT), lower-limb spasticity and muscle force, postural sway tests, Modified Motor Assessment Scale (MMAS), and FIM instrument scores were recorded before, during, and after the rehabilitation and at 6 months follow-up. The mean walking distance at the end of treatment period was greatest for patients in the GTstim and GT groups (6900 and 6500 m) vs. 4800 m. The body-weight support was individually reduced from 30% to 9% of the body weight over the course of the program. The 10MWT, 6MWT, MMAS, dynamic balance test time and test trip (P=.005) scores improved similarly for all patients, regardless of group assignment. However, no differences were found between the groups. Patients' motor performance remained improved at the follow-up.</td>
</tr>
<tr>
<td>Tong et al. (2006)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>4</td>
<td>Acute</td>
<td>46</td>
<td>46 acute stroke patients were randomly assigned to 1 of 3 groups: i.) conventional gait training (CGT) (n=20), ii.) gait training using an electrical gait trainer (EGT) (n=15), or iii.) gait training using an electromechanical gait trainer with functional electric stimulation (EGT-FES) (n=15). Each group received 40 min of regular physiotherapy. The experimental treatment was given 20 min/day, 5 days/wk for 4 weeks. Outcome measures included five-meter walking speed test, elderly mobility scale (EMS), motricity index leg subscale, functional ambulatory category (FAC). There were significant between-group differences for the EGT and EGT-FES groups in the FAC compared to the CGT group and for the EGT-FES group in walking speed compared to the CGT group following 2 weeks of treatment. After the fourth week of treatment, significant improvements were seen for both interventions compared to the control (CGT) in the FAC, walking speed, and EMS. There was a significant improvement in the Motricity Index for the EGT-FES group compared to the CGT group.</td>
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</table>
| Bae et al. (2014)              | South Korea   | RCT          | 8           | 9.8mo  | 20    | Population: Experimental Group (EG; N=10): Mean age=45.4±19.7yr; Gender: Males=6, Females=4. Control Group (CG; N=10): Mean age=52.0±16.1yr; Gender: Males=7, Females=3. Intervention: Participants were randomly allocated either to the EG and received robot-assisted gait training (RAGT) combined with functional electrical stimulation (FES) applied on the affected dorsiflexor, or to the CG and received RAGT only. Both groups received the 1. The MMAS, TUG, and the BBS improved significantly after the intervention compared to before the intervention in both groups. 2. The gait speed, stride length, and the maximal knee flexion improved in the EG and CG. 3. Only the EG demonstrated an improvement on the step length (p=0.010), and the maximal knee extension (p=0.018) after the intervention. 4. Only the maximal knee flexion at post
therapies for 30 min/day, 3 days/week, for 5 weeks. Additionally, all participants received conventional physical therapy. Assessments were conducted before and after the 15 sessions for 5 weeks.

**Outcomes:** Modified motor assessment scale (MAS); Timed Up-and-Go test (TUG); Berg Balance scale (BBS); temporal gait parameters (i.e. gait speed, cadence, step length, stride length, double support); kinematic gait parameters.

### Other Training

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kunkel et al.</strong> (2013)</td>
<td>Exercises + FES (N=7): Mean age=64.0±15.5yr; Gender: Males=4, Females=3. Exercises (N=7): Mean age=71.1±18.8yr; Gender: Males=4, Females=3. Usual Care (N=7): Mean age=70.0±10.6yr; Gender: Males=4, Females=3.</td>
<td>To identify parameters for the design of a larger trial: 1) identifying eligible participants, recruitment, retention rates; 2) the feasibility and acceptability of delivering functional electrical stimulations (FES) to the gluteus maximus and quadriceps femoris for acute stroke patients in a hospital rehab setting; 3) the outcome measures; 4) obtaining initial estimates of effect size; 5) clarifying the relevant CG. Participants were randomized into one of three groups: Exercises &amp; Functional Electrical Stimulation (FES); Exercise-alone group; Control (Usual care) group. The Exercises &amp; FES group was the delivery of FES in combination with the exercise program administered to the exercise-only group. The exercise-alone participants focused on exercises that were geared at improving standing balance ability and stability, and also increasing weight transferred onto the affected lower limb. The CG received usual care which was delivered by the National Health Service therapists; included techniques that enabled independent movement (i.e. standing and walking practice, using the Bobath approach).</td>
<td>1. There were no statistically significant differences in the ability to walk between the three groups over time. 2. Between-group differences in weekly increases in striding stance were not statistically significantly different either. 3. FES was not as frequently or intensively delivered as planned, in regards to the Feasibility and Acceptability of delivering FES and outcome measures. 4. Findings suggest that there is a short window of opportunity where patients can receive the intervention and achieve a medically stable state, achieve mobility milestones, and achieve discharge within a short period of time to discharge. 5. There were no trends in favor of the FES group. The study was not powered for effectiveness and even with a lack of statistical significance; this does not mean that the treatment is non-effective.</td>
</tr>
<tr>
<td><strong>Chung et al.</strong> (2015)</td>
<td>Brain-computer interference-based functional electrical stimulation (BCI-FES; N=5): Mean age=43.6yr; Gender: Males=4, Females=1. (FES; N=5): Mean</td>
<td>The BCI-FES group showed significant differences after the intervention on the TUG (p&lt;0.05), cadence (p&lt;0.05), and side step length on the affected side (p&lt;0.05).</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Design</td>
<td>PEDro</td>
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<tr>
<td>Mrachacz-Kersting et al. (2015)</td>
<td>Denmark</td>
<td>PCT</td>
<td>No Score</td>
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<tr>
<td>Sheffler et al. (2006)</td>
<td>USA</td>
<td>PCT</td>
<td>No Score</td>
</tr>
<tr>
<td>Everaert et al. (2013)</td>
<td>Canada</td>
<td>RCT</td>
<td>PEDro=7</td>
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</table>
During assessment, walking performance was tested with the device on and off. Outcome measures included Figure-8 Walking Speed (Fig-8), Ten-Meter Walking Speed (10-m), and Modified Rivermead Mobility Index.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS Mean</th>
<th>N Start</th>
<th>N End</th>
<th>Population</th>
<th>Intervention</th>
<th>Outcomes</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kluding et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
<td>5</td>
<td>4.55±4.72yr</td>
<td>197</td>
<td>197</td>
<td>197 individuals with stroke (mean=4.55±4.72yr) were randomized to one of two groups. Both groups received six weeks of dose-matched physical therapy sessions on AFO education and gait training. Then, for 30 weeks individuals received either surface FES (N=99) or a standard AFO (N=98). At 30 weeks, individuals using an AFO were crossed over to also receive FES; those originally in the FES group continued to receive FES. Repeated measures were conducted at 6, 12, and 30 weeks which included 10-meter walk test, Fugl-Meyer Score, Timed Up and Go, 6-minute walk test, and the Berg Balance Scale.</td>
<td>Both groups demonstrated significant improvement in all outcome measures at 30 weeks although there was no significant difference between groups.</td>
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<tr>
<td>Salisbury et al. (2013)</td>
<td>UK</td>
<td>RCT</td>
<td>6</td>
<td>51.7d</td>
<td>16</td>
<td>14</td>
<td>Population: Experimental group (EG; N=9): Mean age: 55.8±11.3yr; Gender: Males=3, Females=6. Control Group (CG; N=7): Mean age=52.6±17.2yr, Gender: Males=3, Females=4. Intervention: Participants were randomly allocated to either the CG or EG. The CG received routine gait re-education as part of physiotherapy rehabilitation (5 days a week, 20 minutes per session). The EG received the same routine gait re-education as the CG with a functional electrical stimulation (FES) orthotic device for the correction of the dropped foot during routing gait re-education. Participants were assessed at week 0, week 6, and week 12. Outcomes: Timed 10 meter walk test (10MWT); Functional ambulation classification (FAC); Stroke impact scale (SIS); Visual analogue scale (VAS).</td>
<td>1. No statistically significant differences between groups were found on any of the outcome measures. 2. Only the FAC and the SIS had the potential to be completed at all time-points. The FAC achieved the highest completion levels (88-100%), while the SIS achieved lower completion rates.</td>
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<tr>
<td>Sheffler et al. (2013a)</td>
<td>USA</td>
<td>PCT</td>
<td>No Score</td>
<td>41.3±53.5mo</td>
<td>12</td>
<td>1</td>
<td>Population: Mean age=47.6±8.9yr; Gender: Males=8, Females=4. Intervention: Participants performed gait analysis with transcutaneous peroneal nerve stimulation (TPNS), ankle foot orthosis (AFO), or no device. Outcomes were assessed efrore and after treatment. Outcomes: Gait parameters.</td>
<td>1. There was a significant difference in stride length between conditions (F=4.812, p=0.021), with significant improvements using TPNS and AFO compared to no device. 2. There was no device effect on gait velocity or cadence. 3. There was no device effect on peak hip flexion in swing, peak knee flexion in swing, peak dorsiflexion in swing, peak knee extension in stance, or peak hip power.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bethoux et al. (2014)</td>
<td>US</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Population: WalkAide FES (WA; N=242): Mean age=63.87±11.33yr; Gender:</td>
<td>1. No statistically significant between-group (WA vs. AFO) differences were observed for</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
RCT
PEDro=6
TPS\textsubscript{WA}=6.90yr
TPS\textsubscript{AFO}=6.86yr
N\textsubscript{Start}=495
N\textsubscript{End}=399

Males=147, Females=95. Ankle foot orthosis (AFO; N=253): Mean age=64.30±12.01yr; Gender: Males=157, Females=86. **Intervention**: Participants were randomly allocated to one of the two groups, where one group wore the WalkAide functional electrical stimulation (FES) system (WA), and the other wore the ankle foot orthosis (AFO) brace on the lower leg. Participants were followed up for 6 mo and study measures were performed at screening (without device), baseline (postfitting, with device), 1, 3, and 6 mo with device. **Outcomes**: 10 meter walk test (10MWT); mobility, activity of daily living/ instrumental activites of daily living (ADL/IADL); social participation domain scores of the stroke impact scale (SIS); device-related serious adverse event (SAE) rate; 6 minute walk test (6MWT), GaitRite functional ambulation profile (FAP); modified Emory functional ambulation profile (mEFAP); Berg balance scale (BBS); Timed Up-and-Go test (TUG); stroke-specific quality of life (SSQoL), and individual SIS domain scores (strength, mobility, communication, emotion, memory and thinking, social participation, ADL/IADL, and hand function).

**2.** Both WA and AFO groups demonstrated a significant improvement in gait velocity from screening to 6 mo.

**3.** Only the WA group improved on the SIS score from screening to 6 mo (p<0.05).

**4.** Based on the gait velocity, and SIS, the WA was not found to be inferior to the AFO group.

**5.** In both groups, significant differences were found between baseline and 6 mo for the 6MWT and for the FAP.

**6.** The WA group improved from baseline to 6 mo on the mEFAP, mEFAP floor time, mEFAP carpet time, mEFAP obstacle course, mEFAP stair time, BBS, SIS strength, and SIS mobility.

**7.** No significant between-group differences were found for these variables except for the mEFAP obstacle course time (p=0.004).

**Table 9.7.2.1** Summary of Studies Evaluating Neuromuscular Electrical Stimulation

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Schiemanck et al., (2015) Netherlands</strong></td>
<td>Population: Mean age=49.7±14.3yr; Gender: Males=4, Females=4. <strong>Intervention</strong>: Gait quality when analyzed while the participant was using implantable functional electrical stimulation (FES) called the ActiGait. Use of the ActiGait system was built up gradually in a 3wk period from 15-60min/d to 6hr/d. After 3wk, participants had the choice to continue with FES or use their AFO. Outcomes were assessed at baseline (T0), 2wk (T1), 8wk (T2), and 26wk (T3). <strong>Outcomes</strong>: Maximum paretic ankle plantarflexion; peak ankle plantarflexion power; 10 Metre Walk Test (10MWT); 6 Minute Walk Test (6MWT); step length.</td>
<td>1. Maximum paretic ankle plantarflexion was larger with FES than with AFO (p=0.005) over time. 2. Peak ankle plantarflexion power was higher with FES than an AFO (p=0.048) over time. 3. Step length was significantly smaller with FES than with and AFO over time (p=0.0011) over time. 4. Walking speeds were significantly different between participants using FES and those wearing AFOs, favouring those using FES (p&lt;0.05) over time.</td>
</tr>
<tr>
<td>Time Post Stroke (TPS)</td>
<td>Sample Size (N)</td>
<td>Details</td>
</tr>
<tr>
<td>------------------------</td>
<td>-----------------</td>
<td>---------</td>
</tr>
<tr>
<td>Chen et al. (2005)</td>
<td>Taipei, RCT, PEDro=4, TPS&gt;1yr, N=24</td>
<td>24 patients, at least one-year post stroke were randomized to receive 20 min of electrical stimulation (ES) daily, 6X/week x 1 month or to placebo ES. Patients were included if they had ankle spasticity of grades 2 or 3 (modified Ashworth scale). Performance on 10 m timed walk was assessed at the end of the treatment period. In the active ES group, 8/12 patients demonstrated a decrease in spasticity compared to only 1/12 patient in the placebo ES group. Although between group differences in walking speed were not reported, patients in the active group demonstrated a significant improvement (89.8 to 80.8 sec), while patients in the control group did not (87.9 to 88.1 sec).</td>
</tr>
<tr>
<td>Yavuzer et al. (2006)</td>
<td>Turkey, RCT, PEDro=7, TPS&lt;6mo, N=25</td>
<td>25 patients (&lt;6 months post stroke) were randomized into 1 of 2 groups: 1) a neuromuscular electric stimulation (NMES) of the tibialis anterior muscle or 2) Control. Patients received a traditional therapy program 5 days/week for 4 weeks, the NMES group also received NMES treatment for 10 min. Outcomes included Lower-extremity motor recovery (Brunnstrom stages for lower extremity) and gait kinematics. No significant between-group differences were found. Patients in both groups showed improvements on the Brunstrom stages of motor recovery (p&lt;0.05) after the 4-week treatment period with 58% of the NMES group and 61% of the control group showing improvement in voluntary ankle dorsiflexion.</td>
</tr>
<tr>
<td>Mesci et al. (2009)</td>
<td>Turkey, RCT, PEDro=5, TPS=Chronic, N=40</td>
<td>40 patients with chronic stroke all received a conventional rehabilitation program for a 4-week period. In addition to this rehabilitation program, 20 patients were randomized to receive NMES treatment for hemiplegic foot dorsiflexor muscles for 4 weeks, 5 days a week. The other 20 patients received no additional treatment. Sessions were performed as one session per day and added to a total of 20 sessions. Clinical parameters were evaluated before and after the treatment. Outcomes assessed included ankle passive dorsiflexion ROM, Modified Ashworth Scale (MAS), FIM, Functional Ambulation Categories (FAC), Rivermead Motor Assessment score. There was a significant improvement from pre to post test, favouring the NMES group on the following outcomes: ankle dorsiflexion ROM, MAS score, lower extremity Brunstrom stage, and FIM score.</td>
</tr>
<tr>
<td>Yamaguchi et al. (2012)</td>
<td>Japan, RCT, PEDro=8, TPS=Subacute, N=27</td>
<td>27 patients with sub acute stroke (&lt;6 months post stroke) were randomized into one of three groups (a) electrical stimulation with passive locomotion like movement (n=9) (b) electrical stimulation alone (n=9), (c) passive locomotion-like movement alone (n=9). The soleus muscle was stimulated in the FES groups. Each session lasted 20 minutes. The 10 meter walk test and the modified Ashworth Scale were used before and after sessions to assess maximum gait speed and tone of</td>
</tr>
<tr>
<td>Study</td>
<td>Location</td>
<td>Study Design</td>
</tr>
<tr>
<td>------------------------------</td>
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</tr>
<tr>
<td>Knutson et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
</tr>
<tr>
<td>Suh et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
</tr>
<tr>
<td>Gurcan et al. (2015)</td>
<td>Turkey</td>
<td>RCT</td>
</tr>
<tr>
<td>Ko et al. (2016)</td>
<td>Korea</td>
<td>RCT</td>
</tr>
</tbody>
</table>
9.8 Sensorimotor Stimulation

9.8.1 Transcutaneous Electrical Nerve Stimulation (TENS)

Table 9.8.1.1 TENS Treatment to Enhance Mobility

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tekeoğlu et al. (1998)</td>
<td>Turkey</td>
<td>RCT</td>
<td>PEDro=9</td>
<td>TPS=30-240d N=60</td>
<td>A double blind randomised controlled trial of 60 patients. Patients received either basic neurophysiological rehabilitation or received in addition to the basic neurophysiological rehab treatment, active TENS for 40 sessions over 8 weeks with a frequency of 100Hz at intensity that</td>
<td>At 8 weeks, patients in both groups had significantly improved their BI scores compared to baseline. Patients in the treatment group experienced greater improvement in BI scores compared to the control group. Significant reduction in Ashworth scores was observed in</td>
</tr>
<tr>
<td>Study Authors</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro</td>
<td>TPS</td>
<td>Sample Size</td>
<td>Results</td>
</tr>
<tr>
<td>-----------------------</td>
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<tr>
<td>Johansson et al. (2001)</td>
<td>Sweden</td>
<td>RCT</td>
<td>8</td>
<td>5-10d</td>
<td>N=150</td>
<td>150 patients were randomized to receive either acupuncture (including electroacupuncture), high-intensity, low-frequency TENS that induces muscle contractions; or low-intensity (subliminal) high-frequency electrostimulation (control group). No significant differences were observed between groups on any of the outcome measures (Rivermead Mobility Index, Walking Ability, Barthel Index, Nottingham Health Profile, Nine Hole Peg Test).</td>
</tr>
<tr>
<td>Ng &amp; Hui-Chan (2007)</td>
<td>China</td>
<td>RCT</td>
<td>6</td>
<td>Chronic</td>
<td>N=88</td>
<td>88 patients with chronic stroke were assigned randomly to receive a home-based program of i) TENS, ii) TENS+ task-related training (TRT), iii) placebo TENS+TRT, or iv) 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. 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. 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. When compared with all 3 groups, the TENS+TRT group showed significantly greater improvement in gait velocity.</td>
</tr>
<tr>
<td>Ng &amp; Hui-Chan (2009)</td>
<td>USA</td>
<td>RCT</td>
<td>7</td>
<td>Chronic</td>
<td>N=109</td>
<td>109 chronic, hemiparetic stroke survivors with spastic plantarflexors were assigned randomly to: (1) transcutaneous electrical nerve stimulation (TENS) (n=29), (2) TENS + exercise (n=28), (3) placebo stimulation + exercise (n=25), or (4) control group (n=27). Subjects in the TENS group received 60 minutes of electrical stimulation. Both the TENS + exercise group and placebo stimulation + exercise group did 60 minutes of exercises, followed respectively by 60 minutes of electrical and placebo stimulation. Treatment was given five days a week for four weeks and was home-based. The control group had no active treatment. The primary outcome was comfortable gait velocity, measured at baseline, weeks 2 and week 4. Walking endurance and functional mobility were measured by the distance covered during a 6-minute walk test (6MWT) and by timed up and go test. Only the combined TENS + exercise group showed significantly greater absolute and percentage increases in gait velocity (by 37.1-57.5%, all P&lt;0.01) and reduction in timed up and go scores (by -14.9 to -23.3%, P&lt;0.01) from week 2 onwards. When compared with the control and TENS groups, only the combined TENS + exercise group covered significantly more distance in the 6MWT (by 22.2-34.7%, P&lt;0.01) from week 2 onwards.</td>
</tr>
<tr>
<td>Yan &amp; Hui-Chan (2009)</td>
<td>China</td>
<td>RCT</td>
<td>6</td>
<td>Mean=9.2d</td>
<td>N=62</td>
<td>62 patients, an average of 9.2 days post-stroke, were randomly assigned to 3 groups receiving (TENS), placebo stimulation (PS), or standard rehabilitation (SR) alone. Stimulation was applied to 4 acupuncture points in the affected lower leg for 60 min, 5 days a week for 3 weeks. Plantarflexor spasticity, ankle muscle strength, and functional mobility were measured before treatment, weekly during treatment, and at follow-up at week 8 post stroke. Compared with SR or PS groups, a significantly greater percentage of subjects in the TENS group achieved normal tone, increased ankle dorsiflexor strength, and decreased antagonist co-contracture ratio compared with the PS or SR groups. The patients in the TENS group also tended to walk 2-4 days earlier than the patients in the other 2 groups.</td>
</tr>
<tr>
<td>Cho et al. (2013)</td>
<td>Korea</td>
<td>RCT</td>
<td>5</td>
<td></td>
<td>N=222</td>
<td>Population: Transcutaneous electrical stimulation group (TENS; N=22): Mean age=55.2±11.49yr; Gender: Males=14, Females=8. Placebo-TENS group (N=220): Mean 1. Both the TENS group and the placebo-TENS group demonstrated a significant change in the MAS scores from baseline to post-training, from baseline to follow-up, and</td>
</tr>
<tr>
<td>TPS_{TENS} = 15 \text{ mo}</td>
<td>TPS_{Placebo-TENS} = 13.9 \text{ mo}</td>
<td></td>
<td></td>
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<td>--------------------------</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N_{Start} = 50</td>
<td>N_{End} = 42</td>
<td></td>
<td></td>
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</tbody>
</table>

**Intervention:** Participants were randomly allocated either to the EG and received transcutaneous electrical stimulation (TENS), or to the CG and received placebo-TENS where the electrodes were placed in the same location (i.e. muscle belly of the gastrocnemius) as in the TENS group but no electrical stimulation was administered. Both groups received physical therapy for 30 minutes before the TENS application. Participants were assessed before the intervention, after the intervention, and one day after the intervention.

**Outcomes:** spasticity, balance: postural sway length (while standing, with eyes open, with eyes closed, on an unstable surface with eyes open); Modified Ashworth Scale (MAS); hand held dynamometer (HHD).

1. Significant increase in ankle passive dorsiflexion range of motion after therapy within both groups (p<0.05) but no significant difference between groups after intervention.
2. MAS showed the second maximally significant mean group value (p=0.001).
3. Parameters were statistically more significant in the EG vs CG.

**Hussain et al.** (2013)

<table>
<thead>
<tr>
<th>China</th>
<th>RCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEDro = 6</td>
<td>TPS_{EG} = 5.01 \text{ mo}</td>
</tr>
<tr>
<td>TPS_{CG} = 4.45 \text{ mo}</td>
<td>N_{Start} = 35</td>
</tr>
<tr>
<td>N_{End} = 30</td>
<td></td>
</tr>
</tbody>
</table>

**Population:** Experimental Group (EG; N=15): Mean age=53.6\text{ yr}; Gender: Male=8, Female=7. Control Group (CG; N=15): Mean age=57.6\text{ yr}; Gender: Male=10, Female=5.

**Intervention:** Control-Bobath therapy. Experimental-Both Bobath and transcutaneous electrical nerve stimulation (TENS) therapy. Both groups received treatment for 4wks, 5d/wk. Bobath therapy-15min passive movement of big toe and remaining toe extension, ankle joint dorsiflexion, knee joint extension and hip joint abduction and external rotation. TENS therapy-30min, delivered through 2 pairs of electrodes attached at acupoints selected from post-training to follow-up (TENS: all p<0.05; Placebo-TENS: all p<0.05).

2. The MAS scores in the TENS group were significantly lower than those in the placebo-TENS group at posttraining however, no difference between the two groups was found at follow-up (p<0.05; refer to mean values above).

3. Both the TENS group and the placebo-TENS group demonstrated a significant improvement in HHD from baseline to posttraining, and from baseline to follow-up (TENS: all p<0.05; Placebo-TENS: all p<0.05).

4. The HHD was significantly lower in the TENS group compared to the placebo-TENS group at post-training (p<0.05; refer to mean values above). The difference between the two groups was found to be significant at follow-up.

5. TENS with eyes open and eyes closed showed significant improvements in sway length from baseline to follow-up which was not observed in the placebo-TENS group (eyes open: all comparisons p<0.05; eyes closed: all comparisons p<0.05). Only the posttraining values during the eyes closed condition were significantly lower in the TENS group compared to the placebo-TENS group (p<0.05).

6. During the unstable surface with eyes open condition, both the TENS group and the placebo-TENS group demonstrated a significant difference in postural sway length from baseline to posttraining only (TENS: p<0.05; Placebo-TENS: p<0.05).

7. No other significant difference between groups on outcomes and time points were observed.
according to traditional acupuncture and previous studies. **Outcomes:** Ankle-joint dorsiflexion range of motion, strength of ankle dorsiflexor muscles, motor function of the lower limb and walking speed: hand-hold goniometer for ankle dorsiflexion, manual muscle strength testing scale for strength of ankle dorsiflexors; Brunnstrom stage for motor function of lower limb.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>TPSg</th>
<th>TPSplacebo</th>
<th>Nstart</th>
<th>Nend</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tyson et al. (2013)</strong></td>
<td>UK</td>
<td>RCT</td>
<td>6</td>
<td>Chronic</td>
<td>29</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Park et al. (2014)</strong></td>
<td>India</td>
<td>RCT</td>
<td>7</td>
<td>Chronic</td>
<td>Placebo</td>
<td>34</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td><strong>Chan et al. (2015)</strong></td>
<td>Korea</td>
<td>RCT</td>
<td>8</td>
<td>Chronic</td>
<td>Placebo</td>
<td>37</td>
<td>37</td>
<td></td>
</tr>
</tbody>
</table>

**Population:** 29 individuals with chronic stroke were randomized to receive a single session of either active TENS or control treatment (sham TENS). Individuals were crossed over to receive both treatment protocols. TENS was applied using the Biostim® M7 TENS unit, an ankle-length sock that stimulates the entire foot and ankle. Muscle strength (dynamometer), balance (Standing Forward Reach Test), and mobility (10-m walk test) were assessed immediately post treatment. Individuals improved on balance (p=0.009), mobility (p=0.002), and plantarflexor strength (p=0.008), but not dorsiflexor strength (p=0.194).

1. Greater improvements in spasticity denoted by reduced MAS scores were found in the TENS group compared to the placebo group (p<0.05).

1. Both TENS+TRTT and the placebo-TENS+TRTT groups showed a significant improvement at A1, A2 and Afu on the PTFT, PTET, and TIS scores (p<0.05).
2. Only the TENS+TRTT demonstrated significant improvement at A1, A2 and Afu on the LSRA (p<0.05).
3. Both groups (TENS+TRTT, and placebo-TENS+TRTT) also showed significant differences in ΔMs at A1, A2, and Afu compared to the control placebo group on the PTFT, PTET, TIS, and LSRN (p<0.025).
4. When compared to the placebo-TENS+TRTT group, the TENS+TRTT group showed earlier and greater improvements in the TIS score at A1 (p<0.025) but not in other outcomes.
5. The FSR and the SSB scores of the TENS+TRTT group and the placebo-
training sessions per week, for 6 weeks, totalling to 30 sessions. Each session lasted 1 hour. Participants were assessed at baseline (A0), after 3 weeks (A1), after 6 weeks of training (A2), and at 4 weeks after the intervention (Afu).

**Outcomes**: trunk muscle strength, functional seated reaching distance, and trunk motor control: isometric peak trunk flexion torque (PTFT); peak trunk extension torque (PTET); forward sitting functional reach (FSR); lateral seated reaching of affected side (LSRA); lateral seated reaching to unaffected side (LSRN); trunk impairment scale (TIS); static sitting balance (SSB); dynamic sitting balance (DSB); coordination (CO).

TENS+TRTT group were not significantly different at any time points when compared to baseline or when compared to the control values (p<0.025).

6. Both groups (TENS+TRTT, and placebo-TENS+TRTT) demonstrated a significant improvement from baseline at A1, A2 and Afu on the DSB and on the CO (all p<0.05).

7. Both groups (TENS+TRTT and placebo-TENS+TRTT) demonstrated a significant difference compared to the control values on the DSB at A1, A2, and Afu while on the CO, only the TENS+TRTT was significantly different compared to the control (p<0.025).

8. When compared to the placebo-TENS+TRTT, the TENS+TRTT showed a significant difference on the CO at A1, A2 and Afu (all p<0.025).

### Laddha et al. (2016)

**India**

RCT

PEDro=5

TPS=15.7±10.1mo

Nstart=52

Nend=30

**Population**: Mean age=46.46±6.9yr, Gender: Males=19, Females=11.

**Intervention**: Participants randomly assigned to receive task oriented exercises alone (CG; N=10), 30min of transcutaneous electrical nerve stimulation (TENS) and task oriented exercises (E1; N=10), or 60min of TENS and task oriented exercises (E2; N=10). All groups completed 5 sessions/wk for 6wk. Outcomes were assessed at baseline, 3wk, and 6wk.

**Outcomes**: Modified Ashworth Scale (MAS); Timed-Up-and-Go Test (TUG).

1. There was a significant improvement in plantar flexor MAS scores at 6wk in all groups (p<0.05); however, there was a significantly greater improvement in E2, followed by E1 compared to CG (p<0.05).

2. There was a significant improvement in dorsiflexor MAS scores at 6wk in all groups (p<0.05); however, there was a significantly greater improvement in E2, followed by E1 compared to CG (p<0.05).

3. There was a significant improvement in the TUG test over time in all groups (p<0.05); however, there was a no significant difference between groups (p=0.465).

### 9.8.2 Other Sensorimotor Stimulation

**Table 9.8.2.1 Summary of Studies Evaluating Other Sensorimotor Stimulation**

<table>
<thead>
<tr>
<th>Author, Year Country Study Design (PEDro) Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vibration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Van Nes et al. (2006)</strong> Netherlands RCT PEDro=9 TPS&lt;6wk N=53</td>
<td>53 patients were randomized to receive either whole-body vibration (n=27) or exercise therapy on music (n=26) in addition to a regular inpatient rehabilitation program. Whole-body vibration, was used as a novel method of somatosensory stimulation to improve postural control and activities of daily living The whole-body vibration group</td>
<td>Both at 6 and 12 weeks follow up, no clinically relevant or statistical differences in outcome were observed between the groups.</td>
</tr>
</tbody>
</table>
received 4×45-second stimulation on platform vibration device, 5 days per week during 6 weeks. Outcome variables included the Berg Balance Scale, Trunk Control Test, Rivermead Mobility Index, Barthel Index, Functional Ambulation Categories, Motricity Index, and somatosensory threshold at 0, 6, and 12 weeks follow up.

<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Outcome Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tihanyi et al. (2007)</td>
<td>Hungary</td>
<td>RCT</td>
<td>5</td>
<td>27.2±10.4d</td>
<td>16</td>
<td>Isometric and eccentric knee extension torque increased 36.6% and 22.2%, respectively, after vibration (p&lt;0.05) and 8.4% and 5.3% in the control group. Vibration increased EMG amplitude 44.9% and the median frequency in the vastus lateralis by 13.1% (all P&lt;0.05) without changes in the control group (10.6% and 3.9%). Vibration improved the ability to generate mechanical work during eccentric contraction (17.5%). Vibration reduced biceps femoris co-activation during isometric (8.4%, ns) and eccentric (22.5%, p&lt;0.05) contraction.</td>
</tr>
<tr>
<td>Lau et al. (2012)</td>
<td>Hong Kong</td>
<td>RCT</td>
<td>8</td>
<td>&gt;6mo</td>
<td>82</td>
<td>There were significant improvements in balance, dynamic postural control, mobility, muscle strength and fall-related self-efficacy over time for both groups (p&lt;0.05). There were no significant differences between intervention or control groups on any outcome measure (p&gt;0.05).</td>
</tr>
<tr>
<td>Lee et al. (2013a)</td>
<td>Korea</td>
<td>Population: Local vibration stimulus training program group (LVSTP; N=16):</td>
<td></td>
<td></td>
<td></td>
<td>1. A significant effect of time was observed in the LVSTP group for postural sway velocity</td>
</tr>
</tbody>
</table>
Mean age=53.31±8.37yr; Gender: Males=13, Females=3. Control Group (CG; N=51): Mean age=55.73±8.27yr; Gender: Males=11, Females=4.

**Intervention:** Participants either received a local vibration stimulus training program (LVSTP), or received sham local vibration stimulus training. The intervention lasted for 30 minutes/day, 3 days/week, for 6 weeks. Subjects in both groups also participated in a standard rehabilitation programme. Participants were assessed at pretest (1 week prior to the intervention) and at post-test (1 day after the intervention period). The pre- and post-tests were performed with eyes-open and with eyes-closed.

**Outcomes:** Postural sway and gait: postural sway velocity; postural sway distance; gait speed; cadence; paretic side step length; single limb support time.

2. The post-test values for the postural distance and velocity (both eyes closed and open), gait speed, cadence, and p-ingle limb support were significantly different between the LVSTP group and the CG (distance eyes open; distance eyes open; velocity eyes closed; cadence; single limb support (all p<0.05).

3. A significant interaction time x group interaction was found for distance eyes open (p=0.003), distance eyes closed (p<0.001), velocity eyes open (p=0.003), velocity eyes closed (p<0.001), gait speed (p<0.001), cadence (p=0.007), and p-single limb support (p=0.014).

**Marin et al. (2013)**
Spain
RCT
PEDro=6
TPSExp=4.3±2.0yr
TPSCG=4.3±3.0yr
NStart=20
NEnd=20

**Population:** Experimental group (EG, N=11): Mean age=62.3±10.6yr; Gender: Males=6, Females=5. Sham Group (SG, N=9): Mean age=64.4±7.6yr. Gender: Males=5, Females=4.

**Intervention:** The EG received 17 sessions of Whole Body Vibrations (WBV). The CG was exposed to a sham experiment that did not include vibration, but included the same exercises as that of the EG.

**Outcomes:** Muscle architecture, the maximal isometric voluntary contraction of the knee extensors and the Berg Balance Scale (BBS).

1. Overall, there were no statistically significant differences found between groups on the primary outcomes of lower limb muscle architecture, muscle strength, and balance.
2. There were no effects of the intervention or CG on any of the outcomes detected before and after treatment.

**Tankisheva et al. (2014)**
Belgium
RCT
PEDro=6
TPSExp=7.71±8.6yr
TPSCG=7.71±8.6yr
NStart=15
NEnd=15

**Population:** Experimental Group (EG; N=7): Mean age=57.4±13yr; Gender: Males=4, Females=3. Control Group (CG; N=8): Mean age=65.3±3.7yr; Gender: Males=6, Females=2.

**Intervention:** Whole Body Vibration intervention; a training program on a vertical vibration platform 3 times per week for 6 weeks, with a minimum of 1 rest day between training sessions. The CG received no additional training program and made no improvements to lifestyle.

**Outcomes:** Primary outcomes were isometric and isokinetic muscle strength of
the quadriceps (Isokinetic Dynamometer); Additional outcomes were hamstrings muscle strength, static and dynamic postural control (Dynamic Posturography, and Sensory Organization Test (SOT); Isokinetic dynamometer; Dynamic posturography; Ashworth scale; the Functional Ambulation Classification (FAC); theBrunnstrom Fugl-Meyer.

| **Guo et al. (2015)** | **Population:** Experimental Group (EG, N=15): Mean age=53.8±6.0yr. Control Group (CG; N=15): Mean age=54.3±6.0yr. Gender: unspecified. **Intervention:** The EG was treated with whole body vibration while the CG was treated with a placebo. The vibration was given in 60s of vibration with a 10s rest interval, 10 rounds per set, and 8 sets/d. Outcomes were assessed at baseline and post-intervention. **Outcomes:** 10 Metre Walk Test (10MWT); Fugl-Meyer Assessment for the lower extremity (FMA-LE); knee hyperextension times. | 1. The EG improved significantly compared to the CG on the 10MWT (p=0.001) and time of knee hyperextension (p=0.000). 2. There were no significant differences between the EG and CG on the FMA-LE. |
| **Lee (2015)** | **Population:** Experimental Group (EG; N=12): Mean age=59.3±13.2yr; Gender: Males=8, Females=4. Control Group (CG; N=9): Mean age=56.0±9.1yr; Gender: Males=6, Females=3. **Intervention:** Patients were randomized to receive whole-body vibration (EG; 15min/d, 3d/wk) or no additional intervention (CG). Both groups received conventional rehabilitation (30min/d, 5d/wk) for 6wk. Outcomes were assessed before and after treatment. **Outcomes:** Fugl-Meyer Assessment (FMA); Berg Balance Scale (BBS); Timed Up & Go Test (TUGT). | 1. There were significant improvements on FMA, BBS, and TUGT from baseline to follow-up in the EG but not the CG (p<0.05). 2. There was significantly greater improvement on the BBS in the EG than the CG (p<0.05), but not on the FMA or TUGT. |
| **Liao et al. (2016)** | **Population:** Experimental Group 1 (EG1; N=28): Mean age=60.8±8.3yr; Gender: Males=20, Females=9. Experimental Group 2 (EG2; N=28): Mean age=62.9±10.2yr; Gender: Males=18, Females=10. Control Group (CG; N=28): Mean age=59.8±9.1yr; Gender: Males=24, Females=4. **Intervention:** EG1 received low intensity whole body vibration (WBV), EG2 received high intensity WHV, and CG received conventional therapy. Each person received 30 training sessions over an 6-week intervention period. **Outcomes:** Knee extensor isometric, concentric and eccentric strength; 6MWT; Mini-BESTest; ABC and MCS. | 1. There was a significant time effect on knee isometric strength (p=0.001) and flexion (p<0.001) and concentric flexion (p=0.006). 2. There was a significant time effect on TUG, 6MWT, Mini-BESTest, ABC and MCS (p<0.001). 3. There were no significant between-group comparisons for any outcome. 4. There were no significant time effects on the MAS, Frenchay Activity Index, Craig Inventory of Environmental Factors; Short Form 12 Health Survey. |
average 75.5d. Assessments were performed at baseline and post-intervention.

**Outcomes:** Modified Ashworth Scale (MAS); Mini Balance Evaluation Systems Test (Mini-BESTest); Timed Up and Go Test (TUG); 6 Minute Walking Test (6MWT); Activities-specific Balance Confidence scale (ABC); Frenchay Activity Index; Craig Hospital Inventory of Environmental Factors; Short-Form 12 Health Survey; Mental Health composite score (MCS).

**Silva et al.** (2016)  
Brazil  
RCT  
PEDro=6  
TPS>2mo  
N\textsubscript{Start}=35  
N\textsubscript{End}=28

**Population:** Experimental Group (EG; N=18): Mean age=62±9.92yr; Gender: Males=11, Females=7. Control Group (CG; N=10): Mean age=57.4±11.61yr; Gender: Males=6, Females=4.  

**Intervention:** The first phase, which lasted 4wk consisted of four sets of exercises with 60s of vibration. Only the EG received vibration, the CG did not. The second phase was 4wk as well and the number of sets for each exercise was doubled but everything else remained constant. Outcomes were evaluated at baseline and post-intervention.  

**Outcomes:** 6 Minute Walk Test (6MWT); plantar impression area.

1. There were no significant differences in the 6MWT or plantar impression area.

**Chen et al.** (2011)  
Taiwan  
RTC  
PEDro=7  
TPS<4wk  
N=35

35 patients with first-ever stroke onset of <4 weeks who could not ambulate independently received 40 min of OT/PT 5 days a week for 6 weeks. In addition 17 of the patients were randomized to receive daily sessions of thermal stimulation, consisting of alternating hot/cold packs placed on the paretic leg with instruction from the therapist to move the leg away from the stimulus when discomfort developed. Outcomes were assessed at baseline and at 4 and 6 weeks. They included Fugl-Meyer (FM) Assessment score, Modified Motor Assessment Scale the Medical Research Council (MRC) scale for the lower extremity, the Berg Balance Scale (BBS) and Functional Ambulation Classification.

In an analysis of group x time, patients in the thermal group fared significantly better on the FMA, MRC and FAC (p<0.05). Although patients in the thermal group had gained more points on the BBS (28 vs. 15.5, p=0.007), there was no group x time interaction suggesting that BBS scores were only affected by time but not group. There were more independent walkers in the thermal group compared with the control group at 6 weeks (88% vs. .56%, p=0.06).

**Liang et al.** (2012)  
Taiwan  
RCT  
PEDro=7  
TPS=Acute

30 patients were randomized to the intervention and control group. Complete data was available for 25 patients, 13 in the intervention group, 12 in the control group. Intervention involved sessions of The thermal stimulation group experienced statistically significant improvements in lower extremity function and gait ability at week 4 and 6 and at 3 months (p<0.05). There were also significant increases in balance, MMAS and Barthel.
hot and cold stimulation on the paretic leg for 6 weeks (40 minutes per session/5 times per week). One session consisted of 3 cycles of alternating hot and cold packs (8 times each) for 30 second intervals. During each hot or cold pack placement, the patient was asked to move their leg away from the stimuli when the temperature became uncomfortable. Control group received 3 consultations over a 6 week period. Outcomes were assessed before the treatment, and at 4 weeks, 6 weeks, and 3, 6 and 12 month follow-up. Primary outcomes were the Fugl-Meyer Assessment for the Lower Extremity (FMA-LE) and the Medical Research Council Scale for the Lower Extremity (MRC-LE). Secondary outcomes included the Functional Ambulation Classification, BBS, Modified Motor Assessment Scale (MMAS) and the Barthel Index (BI).

1. The EG demonstrated significant improvements from baseline to post-treatment and from baseline to follow-up on the LE-STREAM (p<0.05; p<0.05), on the Mob-STREAM (p<0.05; p<0.05), FAC (p<0.05; p<0.05), and BI (p<0.0). No significant improvement was found regard the PASS and MAS scores. The CG showed no significant improvement on any of the outcome measures.

2. The EG showed greater improvements compared to the CG from baseline to follow-up on the LE-STREAM (p=0.028), the Mob-STREAM (p=0.043), BI (p=0.013), and on the MAS (p=0.034).

Mean MAS scores in the EG decreased significantly from 2.3 before the intervention to 1.4 30 min after the intervention, compared to the insignificant index at 3 months. There were no statistically significant differences between the groups at 6 or 12 month follow-up except for the FMA-LE (p<0.05).
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**Beaulieu et al. (2015)**  
Canada  
RCT  
PEDro=7  
TPS_{EG}=52.9mo  
TPS_{Sham}=82.7mo  
N_{Start}=32  
N_{End}=32

**Population:** Repetitive peripheral magnetic stimulation (RPMS; N=9): Mean age=51±15yr; Gender: Males=4, Females=5. Sham group (N=9): Mean age=55±11yr; Gender: Males=3, Females=6. Healthy group (N=14): Mean age=50±7yr; Gender: Males=6, Females=8.  
**Intervention:** Participants were randomly allocated to the repetitive peripheral magnetic stimulation (RPMS) group or to the sham group, and compared against a healthy CG. Patients in the RPMS group received stimulation over the paretic tibialis anterior (TA) while those in the sham group received sham stimulation. Ankle impairments on the paretic side and ipsilateral TA cortical motor representation were tested clinically twice at the start of the study and at the end of the study, in addition with transcranial magnetic stimulation (TMS) testing before and after the intervention period (i.e. after the first clinical tests, and before the last clinical test). The therapy session lasted 2-3 hours.  
**Outcomes:** Maximum active and passive ankle dorsiflexion range of motion (DF ROM), strength of isometric DF, plantar flexor resistance to high-speed stretch and the associated soleus stretch reflex; active motor threshold (AMT), mean motor evoked potential (MEP) latency, mean peak-to-peak amplitude of the MEP.  

1. A significant group x time interaction was detected for plantar flexor resistance to stretch (p=0.03).  
2. The plantar flexor resistance decreased significantly in the PRMS group (p=0.0007), while the active and passive DF ROM increased significantly from pre to post-therapy (p=0.03). This change was not observed in the sham group.  
3. The RPMS group compared to the healthy controls showed differences for the pre-RPMS plantar flexor resistance (p=0.04), active DF ROM (p=0.002) and DF strength (p=0.0001). Only the DR strength remained below the healthy control values after RPMS (p=0.0006). Sham did differ significantly when compared to the healthy controls.  
4. No effect was observed for either the RPMS group or the sham group on TMS outcomes.  
5. In the RPMS group, changes in DF strength were correlated with the duration of the cortical silent period measured pre-intervention (r=0.81, p=0.016).  
6. DF strength changes were also correlated with AMT changes (r=0.94, p=0.0006).

**Goliwas et al. (2015)**  
Poland  
RCT  
PEDro=6  
TPS_{EG}=4.4±3.1yrs  
TPS_{CG}=4.1±2.8yrs

**Population:** Experimental Group (EG; N=8): Mean age=62.3±9.4yrs; Gender: Males=5, Females=3. Control Group (CG; N=14): Mean age=67.7±9.2yrs; Gender: Males=7, Females=8.  
**Intervention:** Both groups received  

1. A significant change in the percentage difference of WD was seen in the experimental group after intervention compared to baseline in the EO and EC conditions (p<0.05).  
2. There was a significant difference in the...
standard six-week therapeutic rehabilitation. The experimental group received additional sensorimotor foot stimulation (SFS) for 20min/session for 25 sessions. Assessments were made before and after the intervention under 2 conditions: eyes-closed (EC) and eyes-open (EO).

**Outcomes:** Percentage differences in weight distribution (WD) between the affected and non-affected lower extremities; percentage load on the directly affected lower extremity (DL).

3. A significant change in the percentage load on the DL was seen in the experimental group after intervention compared to baseline in the EO and EC conditions (p<0.05).

4. There was a significant difference in the percentage of load on the DL between the two groups after the intervention in the EO condition only (p<0.05).

9.9 Brain Stimulation

9.9.1 Repetitive Transcranial Magnetic Stimulation (rTMS)

**Table 9.9.1.1 Summary of Studies Evaluating Repetitive Transcranial Magnetic Stimulation**

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khedr et al. (2005)</td>
<td>Egypt</td>
<td>RCT PEDro=6</td>
<td>TPS=5-10d</td>
<td>N=52</td>
<td>52 patients with stroke onset of between days 5 and 10 were randomized to receive real or sham rTMS to the affected hemisphere consisting of ten, 10 sec trains of 3Hz stimulation with 50 sec. between each train. The following outcomes were assessed 10 days following treatment: BI, NIH Stroke scale and the Scandinavian Stroke Scale (SSS). There was a significant treatment effect for all outcomes.</td>
</tr>
<tr>
<td>Jayaram &amp; Stinear (2009)</td>
<td>USA</td>
<td>RCT PEDro=5</td>
<td>TPS=Chronic</td>
<td>N=9</td>
<td>9 chronic stroke subjects with persistent hemiparesis received 3 neuromodulatory protocols in random order while walking on a treadmill: inhibitory paired associative stimulation, repetitive transcranial stimulation and anodal transcranial direct current stimulation. Treatment sessions were separated by 2 days. Inhibitory repetitive transcranial magnetic stimulation and inhibitory paired associative stimulation were applied to the contralesional motor system, and facilitatory anodal transcranial direct current stimulation was applied to the ipsilesional motor system. The bilateral modulatory effects of each stimulation protocol were tested on the tibialis anterior, medial gastrocnemius, medial hamstrings, and vastus lateralis up to 20 minutes following treatment. All stimulation protocols increased paretic limb and decreased nonparetic limb motor excitability. There was no statistical difference in the extent of modulation between these stimulation protocols.</td>
</tr>
<tr>
<td>Wang et al. (2012)</td>
<td>Taiwan</td>
<td></td>
<td></td>
<td></td>
<td>24 chronic stroke patients who were able to walk independently for at least 6 m were randomized</td>
</tr>
</tbody>
</table>
RCT PEDro=8
TPS=Chronic
N=24

<table>
<thead>
<tr>
<th>Kakuda et al. (2013)</th>
<th>18 patients with stroke-related gait impairments were included and received both active and sham rTMS. Patients were randomized to the order of receiving active or sham treatment. Treatment involved 10Hz rTMS (2,000 pulses over 20 minutes – 10 sec bursts with 50 sec between bursts) applied to the area of the skull with the most activation of the tibialis anterior muscle of the unaffected lower limb (on the midsagittal plane so bilateral leg stimulation could occur). Outcomes assessed were walking velocity and Physiological Cost Index (PCI) before, after and 10 and 20 minutes after the treatment.</th>
<th>There was a significant increase in walking velocity after active rTMS compared to sham rTMS at all time points (immediately after p&lt;0.001, 10 min after p&lt;0.001, 20 min after p&lt;0.001). There was a significant improvement in PCI after active rTMS compared to sham rTMS at one of the three time points (immediately after p&lt;0.05, 10 min after p=0.134, 20 min after p=0.66).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cha et al. (2014)</td>
<td>Population: High frequency repetitive transcranial magnetic stimulation (HR rTMS; N=12): Mean age=54.83±6.32yr; Gender: Males=6, Females=6. Low frequency repetitive transcranial magnetic stimulation (LF rTMS; N=12): Mean age=51.33±8.71yr; Gender: Males=7, Females=4. Intervention: Participants were randomly allocated to either receive high frequency repetitive transcranial magnetic stimulation (HR rTMS), or to receive low frequency rTMS (LF rTMS). Both groups received balance training for an hour a day, as part of the rehabilitation schedule of the unit. In addition, both groups received the allocated frequency of rTMS (i.e. 10 Hz of high frequency or 1 Hz of low frequency) for a total of 20 sessions for 20 minutes each, once a day, 5 times per week for 4 weeks. Participants were assessed prior to the start of treatment and after the completion of the treatment. Outcomes: Berg balance scale (BBS); Barthel Index (BI); the motor evoked potential (MEP) latency; MEP amplitude.</td>
<td>Both groups demonstrated a significant change from pre to post treatment on the Balance index (p&lt;0.01; p&lt;0.05), and on the BBS (p&lt;0.01; p&lt;0.01). Only the HF rTMS group demonstrated significant changes from pre to post treatment on the latency of EMPs (p&lt;0.05), and on the amplitude of the EMPs (p&lt;0.01). A significant difference in the change in pre to post values between groups was found on all variables (i.e. EMP latency, EMP amplitude, balance index, and BBS) (p&lt;0.05).</td>
</tr>
<tr>
<td>Chieffo et al. (2014)</td>
<td>Population: Real-sham group (N=4): Mean age=60.5±13yr; Gender: unspecified. Sham-real group (N=5): Mean age=62±9.4yr; Gender: unspecified. Intervention: All participants received both real repetitive transcranial magnetic stimulation</td>
<td>A significant improvement in the FM scores from baseline to post-treatment and from baseline to follow-up in the real rTMS group was found (p=0.009, p=0.001). This effect was not found significant in the sham group.</td>
</tr>
</tbody>
</table>
(rTMS) and sham rTMS however, the order of treatment delivery was randomized such that participants either received real rTMS first followed by the sham treatment, or they received sham rTMS first followed by real rTMS. Each rTMS session lasted 30 minutes. Both rounds of treatment lasted 3 weeks, in which 11 sessions were carried out. Participants were assessed at baseline before the start, at the end, and 4 weeks after the first round of treatment, and again before the start, at the end, and 4 weeks after the start of the second round of treatment which began right after the treatment 1 follow-up.

Outcomes: Fugl-Meyer (FM); 10 meter walk test (10MWT); 6 minute walk test (6MWT); adverse events.

Lin et al. (2015) Taiwan RCT PEDro=9 TPS_{EG}=40.6d TPS_{CG}=33.5d N_{Start}=32 N_{End}=31

Population: Experimental Group (EG; N=16): Mean age=58.3±10.8yr; Gender: Males=10, Females=6. Control Group (CG; N=16): Mean age=62.3±11.7yr; Gender: Males=11, Females=5.

Intervention: Participants were randomly allocated either to the EG and received repetitive transcranial magnetic stimulation (rTMS), or to the CG and received sham-rTMS over the same rTMS stimulated region, at the same frequency, and for the same duration. All participants took part in standard physical therapy following stimulation. The intervention period lasted 15 consecutive days. Participants were assessed before the intervention period and after the intervention period.

Outcomes: Postural assessment scale for stroke patients (PASS); balance subscale of the performance oriented mobility assessment (POMA-b), lower extremity (LE) subscale of the Fugl-Meyer assessment (FMA-LE); Barthel Index (BI); Timed Up-and-Go test (TUG).

Choi et al. (2016) Korea RCT crossover PEDro=7 TPS_{G1}=49.6±28.3mo TPS_{G2}=44.0±29.9mo N_{Start}=30 N_{End}=30

Population: Group 1 (G1; N=15): Mean age=67.1±3.8yr; Gender: Males=14, Females=1. Group 2 (G2; N=15): Mean age=68.7±5.2yr; Gender: Males=13, Females=2.

Intervention: Intervention consisted of 10 sessions over 2 weeks of 10Hz real or sham rTMS. G1 received real then sham rTMS, and G2 received sham then real rTMS. Assessment was taken at baseline, one day after the end of each treatment period, and a 1mo follow-up.

Outcomes: Sensory organization test (SOT); directional control (DCL); Berg Balance Scale

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9.9.2 Transcranial Direct Current Stimulation (tDCS)

<table>
<thead>
<tr>
<th>Author(s) and Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>TPS (weeks)</th>
<th>Start (weeks)</th>
<th>End (weeks)</th>
<th>Interventions</th>
<th>Population</th>
<th>Outcomes</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Du et al. (2016)</td>
<td>China</td>
<td>RCT</td>
<td>7</td>
<td>TPS_{EG1}=7(4-16)</td>
<td>N=69</td>
<td>N=55</td>
<td>Each patient received daily rTMS for 5 days. EG1 received 1200 10s pulses of 3Hz ipsilesional rTMS. EG2 received 1200 30s pulses of 1Hz contralesional rTMS. Control group received sham rTMS. Assessment was conducted at baseline, 5d, 1mo, 2mo, and 3mo.</td>
<td>Experimental Group 1 (EG1; N=23): Mean age=56.78±8.47yr; Gender: Males=15, Females=8. Experimental Group 2 (EG2, N=23): Mean age=56.78±124yr; Gender: Males=16, Females=7. Control Group (CG; N=23): Mean age=53.61±13.55yr; Gender: Males=14, Females=9.</td>
<td>EG1 and EG2 showed significant improvements when compared to the CG in the lower limb FMA (p=0.021, p=0.048). EG1 and EG2 showed significant improvements when compared to CG in the upper limb FMA (p=0.005, p=0.011). EG1 and EG2 showed significant increases compared to CG in lower limb MRC at 1mo (p=0.047 for both). EG2 showed significant improvement in the upper limb MRC score at 2mo (p=0.002) and 3mo (p=0.001) compared to CG. Each real rTMS group showed significant improvements over the CG in NIHSS (EG1 p=0.042, EG2 p=0.017). EG1 and EG2 improved compared to CG on the BI(p=0.019, p=0.001) mRS scores were distinctly different between groups at 5d (p=.008), 2mo (p&lt;0.001) and 3mo (p=0.006)</td>
<td></td>
</tr>
<tr>
<td>Guo et al. (2015)</td>
<td>China</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS_{EG}=4.57±1.27</td>
<td>N=15</td>
<td>N=15</td>
<td>EG received 10Hz rTMS on the primary motor cortex for 10 days with conventional treatment and acupuncture. CG received conventional treatment and acupuncture. Assessments were conducted at baseline and post intervention.</td>
<td>Experimental Group (EG; N=7): Mean age=67.71±7.4yr; Gender: Males=3, Females=4. Control Group (CG; N=8): Mean age=66.63±9.24yr; Gender: Males=4, Females=4.</td>
<td>No significant differences between groups in NIHSS and BI. There was a significant increase from baseline to post intervention in the NIHSS, FMA, and BI in both treatment groups (p&lt;0.05). There was a significant increase in EG scores compared to CG scores in FMA (p=0.041).</td>
<td></td>
</tr>
<tr>
<td>Rastgoo et al. (2016)</td>
<td>Iran</td>
<td>RCT crossover</td>
<td>5</td>
<td>TPS_{G1}=30.2±18.3mo</td>
<td>N=20</td>
<td>N=14</td>
<td>G1 received active rTMS first, followed by sham rTMS after crossover. G2 received sham then active rTMS post crossover. Each participant received daily sessions of 1000 pulses of active or sham 1Hz rTMS on the lower extremity motor area. Outcomes were measured at baseline, 1 week post initial intervention, and 1 week post final intervention.</td>
<td>Group 1 (G1, N=10): Mean age=54.6±11.75yr; Gender: Males=8, Females=2. Group 2 (G2; N=10): Mean age=49.7±11yr; Gender: Males=8, Females=2.</td>
<td>There was no significant difference between groups on the MMAS,LE-FMA, or TUG. There is a significant difference in the MMAS, FMA, and TUG from baseline to 1 week post intervention (p&lt;0.05).</td>
<td></td>
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</table>

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### Table 9.9.2.1 Summary of Studies Evaluating Transcranial Direct Current Stimulation

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jayaram &amp; Stinear (2009)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS=Chronic</td>
<td>N=9</td>
<td>9 chronic stroke subjects with persistent hemiparesis received 3 neuromodulatory protocols in random order while walking on a treadmill: inhibitory paired associative stimulation, repetitive transcranial stimulation and anodal transcranial direct current stimulation. Treatment sessions were separated by 2 days. Inhibitory repetitive transcranial magnetic stimulation and inhibitory paired associative stimulation were applied to the contralesional motor system, and facilitatory anodal transcranial direct current stimulation was applied to the ipsilesional motor system. The bilateral modulatory effects of each stimulation protocol were tested on the tibialis anterior, medial gastrocnemius, medial hamstrings, and vastus lateralis up to 20 minutes following treatment.</td>
</tr>
<tr>
<td>Geroin et al. (2011)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=30</td>
<td>30 chronic stroke patients who were able to walk independently for at least 15 m with the use of walking aids received ten 50-minute treatment sessions, five days a week, for two consecutive weeks. Patients in group 1 (n = 10) underwent robot-assisted gait training combined with transcranial direct current stimulation; patients in group 2 (n = 10) underwent electromechanical gait training combined with sham transcranial direct current stimulation; patients in group 3 (n = 10) performed overground walking exercises using the Bobath approach. Outcomes were assessed before and after treatment and again 2 weeks post treatment. The outcomes included the six-minute walking test and the 10-m walking test.</td>
</tr>
<tr>
<td>Tanaka et al. (2011)</td>
<td>Japan</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=8</td>
<td>8 patients with chronic stroke received one session of real (anodal) or sham stimulation, in random order, separated by 1 week. Patients performed knee extension using their hemiparetic leg before, during, and after anodal or sham tDCS of the lower limb motor cortex representation in the affected hemisphere. Affected hand-grip force was also recorded.</td>
</tr>
<tr>
<td>Danzl et al. (2013)</td>
<td>USA</td>
<td>RCT</td>
<td>Population: Active group (N=4): Mean age=64.75±14.86y; Gender: Males=3, Females=1.</td>
<td></td>
<td></td>
<td>1. The active tDCS group’s improvement on the FAC was significantly greater compared to the sham group performance (p=0.028)</td>
</tr>
</tbody>
</table>
Sham group (N=4): Mean age=71±11yr; Gender: Males=1, Females=4.

**Intervention:** Participants were randomly allocated to receive either active transcranial direct current stimulation (tDCS), or sham tDCS. Each stimulation period lasted 20 minutes, after which participants performed locomotor training with a robotic gait orthosis (LT-RGO). The intervention was repeated 3 times per week for 4 weeks. Participants were assessed at baseline before the intervention, at the completion of the intervention and at 1 month follow-up.

**Outcomes:** 10 meter walk test (10MWT); Timed Up-and-Go test (TUG); stroke impact scale (SIC); functional ambulation category (FAC); Berg balance scale (BBS).

[no additional data provided, unclear if improvement is from baseline to post-treatment or from baseline to follow-up].

2. No other difference between groups was found.

3. Several themes emerged from the participant interviews: hope for recovery, desire for innovation, team support, improved participation, and enhanced engagement with locomotor training.

---

**Chang et al. (2015)**

Korea

RCT

PEDro=8

TPS=Early stage

N\(_{\text{Start}}\)=24

N\(_{\text{End}}\)=24

**Population:** Transcranial direct current stimulation (tDCS; N=12): Mean age=59.9±10.2yr; Gender: unspecified. Sham tDCS group (N=12): Mean age=65.8±10.6yr; Gender: unspecified.

**Intervention:** Participants were randomized to receive either transcranial direct current stimulation (tDCS), or to receive sham tDCS. All participants were receiving conventional physical therapy and movement therapy during the study period. Each session lasted 10 minutes, repeated over 10 sessions for 2 weeks. Participants were assessed one day before the start of the treatment, and one day after the completion of all sessions.

**Outcomes:** Fugl-Meyer Assessment (FMA-LE); lower limb motricity index (MI-LE); functional ambulatory category (FAC); Berg balance scale (BBS); gait parameters (i.e. cadence, speed, stride length, step time, step length).

1. MEP latency became shorter and the MEP amplitude became higher from pre to post-treatment in the tDCS group in comparison with the sham group (p=0.000; p=0.048).

2. The improvements on the FMA-LE and MI-LE were significantly higher in the tDCS group compared to the sham group (p=0.023; p=0.031).

3. No significant differences between groups were found regarding the FAC and BBS during the 2-week intervention period.

4. The changes observed in gait parameters (i.e. cadence, speed, stride length, step time, and step length) were not significantly different between the tDCS and the sham group.

5. Significant correlations were found between FMA-LE vs. latency (r=0.672, p=0.000), FMA-LE vs. amplitude (r=0.502, p=0.012), MI-LE vs. latency (r=0.629, p=0.001), and MI-LE vs. amplitude (r=0.585, p=0.003).

---

**Park et al. (2015)**

Korea

RCT

PEDro=4

TPS\(_{\text{TRT}}\)=15.3±8.4mo

TPS\(_{\text{TST}}\)=22.5±14.5mo

TPS\(_{\text{TT}}\)=23.8±16.2mo

N\(_{\text{Start}}\)=24

N\(_{\text{End}}\)=24

**Population:** Task Related Training Group (TRT; N=8): Mean age=61.6±15.8yr; Gender: unspecified. Task Related Training + Sham tDCS Group (TST; N=8): Mean age=57.0±10.0yr; Gender: unspecified. Task Related Training + tDCS Group (TT; N=8): Mean age=59.0±6.0yr; Gender: unspecified.

**Intervention:** All groups received task related training, TRT received no additional therapy, TST received sham tDCS during task related training, and TT received 15 min of tDCS during training. The intervention was carried out for 30min/dy 3x/wk for 4wks for a total of 12 sessions. Assessments were performed at baseline and

1. The TT showed significant improvements in gait velocity, stance phase symmetry profile and swing phase symmetry profile when compared to the TRT group (p<0.05).

2. There were no significant differences among the groups in step length symmetry profile.
post intervention. **Outcomes:** Gait velocity; stance phase symmetry profile; wing phase symmetry profile; step length symmetry profile.

**Picelli et al. (2015)**
Italy
RCT
PEDro=9
TPS_{G1}=61.3±29.3mo
TPS_{G2}=54.8±32.9mo
TPS_{G3}=51.9±41.1mo
N\_Start=30
N\_End=30

**Population:** Group 1 (G1, N=10): Mean age=64.8±6.0yr; Gender: Males=7, Females=3. Group 2 (G2, N=10): Mean age=61.0±7.2yr; Gender: Males=8, Females=2. Group 3 (G3, N=10): Mean age=62.8±11.8yr; Gender: Males=7, Females=3.

**Intervention:** Participants received 20min robot assisted gait training 5x/wk for 2wk. G1 received 2mA anodal tDCS and 2mA sham tsDCS, G2 received sham tDCS and cathodal tsDCS, and G3 received tDCS and cathodal tsDCS. Outcomes were evaluated at baseline (T0), post-intervention (T1), 2wk follow-up (T2), and 4wk (T3).

**Outcomes:** 6 Minute Walk Test (6MWT); Functional Ambulation Category (FAC); Motricity Index (MI); The Ashworth Scale (AS); cadence; support duration.

1. G3 did significantly better than G1 on the 6MWT from T0 to T1 (p=0.015) and from T0 to T2 (p=0.001).
2. There was a significant improvement in the 6MWT for G3 compared to G2 at post-intervention (p=0.010) and follow-up (p=0.015).
3. There were no significant differences between G2 and G1 on the 6MWT.
4. There were no significant differences between groups in the FAC, MI, support duration, or AS for any time interval.
5. There were significant improvements in cadence found in G3 compared to G1 at both T0 to T1 (p=0.003), and T0 to T2 (p=0.016), but not at T0 to T3.
6. There were significant improvements in cadence in G3 compared to G2 at T0 to T1 (p=0.005) and T0 to T2 (p=0.016).

**Saeyes et al. (2015)**
Belgium
RCT crossover
PEDro=8
TPS_{G1}=45.50±21.80d
TPS_{G2}=38.40±15.14d
N\_Start=31
N\_End=31

**Population:** Group 1 (G1; N=16): Mean age=62.00±9.61yr; Gender: Males=9, Females=7. Group 2 (G2; N=15): Mean age=64.53±7.23yr; Gender: Males=8, Females=7.

**Intervention:** All patients received 16 20min sessions of tDCS and 16 sessions of sham tDCS. G1 received tDCS for 4x/wk for 4wk followed by sham for 4x/wk for 4wk, and G2 received sham followed by tDCS. Outcomes were evaluated at baseline, 4wk and 8wk.

**Outcomes:** Tinetti test; Rivermead Motor Assessment (RMA); Trunk Impairment Scale (TIS).

1. Both groups improved significantly on the Tinneti Test, RMA and TIS from baseline to 8wk (p<0.05).
2. There as a significant “time x condition” effect for the Tinetti Test total score (p=0.049), and the leg and trunk subscore of the RMA (p=0.045).
3. There was a significant difference between G1 and G2 at 4wk on the total score of the Tinetti test (p=0.013) and the leg and trunk subscore of the RMA (p=0.026). There were no significant differences between the groups at 8wk.

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### 9.9.3 Galvanic Vestibular Stimulation (GVS)

#### Table 9.9.3.1 Summary of Study evaluating Galvanic Vestibular Stimulation

<table>
<thead>
<tr>
<th>Author, Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Krewer et al. (2013)</td>
</tr>
<tr>
<td>Germany</td>
</tr>
</tbody>
</table>

**Study Design (PEDro):** Randomized crossover

**Time Post Stroke (TPS):** PB=7.2mo, Con=8.2mo

**Sample Size (N):** (N=14): Mean age=68±8yr; Gender: Males=11, Females=3. Control patients (N=10): Mean age=63±11yr; Gender: Males=6, Females=4.

**Intervention:** Participant with pusher behavior (PB) and those without PB were allocated to three

**Population:** Patients with Pusher Behavior (PB) (N=14): Mean age=68±8yr; Gender: Males=11, Females=3. Control patients (N=10): Mean age=63±11yr; Gender: Males=6, Females=4.

**Methods**

1. In the group with PB, no statistical significant difference between the three experimental interventions regarding the SCP were found.
2. The PB group showed significant improvements on the BLS after DGO

---

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[www.ebrsr.com](http://www.ebrsr.com)
interventions ((1) galvanic vestibular stimulation (GS), (2) driven-gait orthosis (DGO) Lokomat, (3) physiotherapy with visual feedback components (PT-vf)) in a pseudo-random order over the course of one week.

**Outcomes:** Scale for Contraversive Pushing (SCP); Burke Lateropulsion Scale (BLS).

3. A significant change from pre-test to post-test for the DGO therapy was found (p=0.011) but not for the PT-vf or the GVS.

### 9.10 Medications for Motor Recovery

#### 9.10.1 Noradrenergic Agents

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crisostomo (1988)</td>
<td>USA</td>
<td>RCT</td>
<td>TPS&lt;10d</td>
<td>N=8</td>
<td>Double blind placebo controlled trial of 8 patients randomized to receive a single oral dose of either 10mg amphetamine or placebo combined with 45 minutes of physiotherapy within 3 hours of drug administration.</td>
<td>Treatment group showed significantly greater improvement in Fugl-Meyer scores than control group.</td>
</tr>
<tr>
<td>Walker-Baston (1995)</td>
<td>USA</td>
<td>RCT</td>
<td>TPS=16-30d</td>
<td>N=10</td>
<td>Double-blind, placebo controlled trial of 10 patients randomized to receive either 10 mg of dextro-amphetamine every 4th day for 10 sessions paired with physical therapy or to receive a placebo every 4th day paired with physical therapy.</td>
<td>After 1-week discontinuation of drug, treatment group demonstrated significantly greater Fugl-Meyer scores and remained higher at 12 month follow up.</td>
</tr>
<tr>
<td>Sonde et al. (2001)</td>
<td>Sweden</td>
<td>RCT</td>
<td>TPS=Subacute</td>
<td>N=39</td>
<td>39 rehabilitating stroke patients were randomized to receive 10 sessions with 10 mg of amphetamine combined with physiotherapy during a 5-week period or to receive physiotherapy plus placebo.</td>
<td>Motor function was assessed at baseline and at the end of treatment. All patients improved significantly over the intervention period. However, amphetamine-treated patients did not show any increase in motor function or ADL compared to the control group, as assessed by the Fugl- Meyer motor performance score and the Barthel Index.</td>
</tr>
<tr>
<td>Martinsson &amp; Wahlgren (2003)</td>
<td>Sweden</td>
<td>RCT</td>
<td>TPS=72h</td>
<td>N=45</td>
<td>45 patients with cerebral ischemia were enrolled within 72 hours after onset of symptoms. Patients were randomized to 1 of 3 dose levels (2.5, 5, or 10 mg of amphetamine twice daily) or placebo for 5 consecutive days. The main focus of the study was the development of adverse events although measures of functional recovery were also assessed: Lindmark motor assessment chart (LMAC), Activity Index (AI) BI, 10 m self-paced walk. Measurements were performed within the first several days and at follow-up at 3 months after stroke.</td>
<td>Mean blood pressure and heart rate increased significantly with dexamphetamine treatment compared with placebo (p&lt; or =0.01). No difference between amphetamine groups and control group regarding adverse events, body temperature, or consciousness level. After 7 days, significant improvement in amphetamine groups on Lindmark Motor Assessment (p=0.025), Scandinavian Stroke Scale (p=0.044), and Activity Index (p=0.009) compared to control group. No significant differences between amphetamine groups and control</td>
</tr>
</tbody>
</table>
Treig et al. (2003)  
Germany  
RCT  
PEDro=9  
TPS<6wk  
N=24  
Patients were randomized to receive amphetamine (10mg) or placebo every fourth day for a total of ten days. Both groups received Bobath-based physiotherapy within 60min after drug intake.  
On the Rivermead Motor Assessment and Barthel Index, there were no significant differences between groups at baseline, after treatment, or at follow-up.

Gladstone et al. (2006)  
Canada  
RCT  
PEDro=7  
TPS=Acute  
N=71  
71 acute stroke patients with hemiparesis were stratified by stroke severity and randomly assigned to receive 10 sessions of physiotherapy 2 days/week for 5 weeks with either 10 mg dextroamphetamine (AMPH) or placebo. The first treatment started 5-10 days following stroke. Outcomes were assessed at baseline, 6 weeks and 3 months. Main outcome measure was Fugl-Meyer (FM) Scale, assessed at baseline, 6 weeks and 3 months.  
There were no between-group significant differences for motor recovery using the FM Scale. In the moderate hemiparesis subgroup a significant between-group differences on upper extremity motor recovery was found (p=0.002). Both groups improved in Independence in Activities of Daily Living and Motor Scores.

Sonde & Lokk (2007)  
Sweden  
RCT  
PEDro=7  
TPS=Acute  
N=25  
25 acute, hemiplegic stroke patients were randomized to receive: i) 20 mg amphetamine + L-dopa placebo + physiotherapy; ii) 10 mg amphetamine + 50 mg L-dopa + physiotherapy; iii) amphetamine placebo + 100 mg L-dopa + physiotherapy; or iv) amphetamine placebo + L-dopa placebo + physiotherapy within 5-10 days of stroke onset. Patients received drugs or placebo 5x/wk along with 30 min physiotherapy. Outcomes included the Fugl-Meyer motor scale and the Barthel Index and were assessed at the end of treatment and follow-up at 3 months.  
Patients in all treatment groups improved from start of treatment to follow-up; however, there was no drug treatment effect associated with motor function or ADL.

Table 9.10.1.2 Summary of Studies Evaluating Methylphenidate

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade et al. (1998)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Acute</td>
<td>N=21</td>
<td>21 patients admitted to a stroke rehabilitation unit were randomized to receive a 3-week course of methylphenidate (max daily dose 30 mg) or placebo, in addition to routine therapy. Motor outcomes, included Fugl-Meyer scale scores (FM) and a modified version of FIM.</td>
</tr>
<tr>
<td>Lokk et al. (2011)</td>
<td>Sweden</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS=15-180d</td>
<td>N=100</td>
<td>100 stroke patients with leg and/or arm paresis, within 15-180 days of stroke onset were randomized to one of 4 groups: Methylphenidate (MPH;n=25), Levadopa (LD;n=25) or, LD (n=25) or MPH+LD (n=25) or placebo (n=25). All drugs were administered 60 minutes before a 45 minute therapy session, scheduled 5 days a week for 5</td>
</tr>
</tbody>
</table>
weeks. Outcomes included Fugl-Meyer (FM), Barthel index (BI), and National Institute of Health Stroke Scale (NIHSS) at were assessed at baseline, 15, 90, and 180.

Table 9.10.1.3 Summary of Studies Evaluating Droxidopa

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miyai et al. (2000)</td>
<td>Japan</td>
<td>PCT</td>
<td>No Score</td>
<td>TPS=2mo</td>
<td>N=13</td>
<td>13 patients received 45-minute sessions of PT and OT 3 days a week. The treatment patients received an oral dose of 200 mg D-threodops (L-DOPS) 2 hours before PT session followed by 2 months of PT and OT without talking L-DOPS. Control patients received PT for 4 months.</td>
</tr>
</tbody>
</table>

9.10.2 Dopaminergic Agents

Table 9.10.2.1 Summary of Studies Evaluating Levodopa

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheidtmann et al. (2001)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Acute</td>
<td>N=47</td>
<td>47 stroke patients with a radiologically verified thromboembolic brain infarction were randomly assigned to receive either levodopa with decarboxylase inhibitor or placebo before daily physiotherapy sessions. After 3 weeks, both groups received a 1 hour physiotherapy session without the medication or placebo.</td>
</tr>
<tr>
<td>Sonde &amp; Lokk (2007)</td>
<td>Sweden</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Acute</td>
<td>N=25</td>
<td>25 acute, hemiplegic stroke patients were randomized to receive: i) 20 mg amphetamine + L-dopa placebo + physiotherapy; ii) 10 mg amphetamine + 50 mg L-dopa + physiotherapy; iii) amphetamine placebo + 100 mg L-dopa + physiotherapy; or iv) amphetamine placebo + L-dopa placebo+ physiotherapy within 5-10 days of stroke onset. Patients received drugs or placebo 5x/wk along with 30 min physiotherapy. Outcomes included the Fugl-Meyer motor scale and the Barthel Index and were assessed at the end of treatment and follow-up at 3 months.</td>
</tr>
<tr>
<td>Lokk et al. (2011)</td>
<td>Sweden</td>
<td>RCT</td>
<td>PEDro=7</td>
<td></td>
<td></td>
<td>100 stroke patients with leg and/or arm paresis, within 15-180 days of stroke onset were randomized to one of 4 groups: Methylphenidate (MPH; n=25), Levadopa (LD; n=25) or, LD (n=25) or</td>
</tr>
</tbody>
</table>
### Table 9.10.2.2 Summary of Studies Evaluating Roniprole

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cramer et al. (2009)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=1-12mo</td>
<td>N=33</td>
<td>33 subjects with moderate motor deficits due to stroke 1 to 12 months prior and were randomized to receive 9 weeks of immediate-release ropinirole or placebo and then followed up for 3 additional weeks. Drug dose (0.25 to 4 mg once daily) was titrated weekly, as tolerated. All subjects received physical therapy for 90 min, 2x weekly for 4 weeks, in addition. The primary end point was gait velocity during the 12 weeks of study participation. Secondary outcomes included gait endurance, Fugl Meyer (FM) scores, SIS, BI and the Hamilton depression Scale.</td>
</tr>
</tbody>
</table>

### 9.10.3 Serotonergic Agents

### Table 9.10.3.1 Summary of Studies Evaluating Citalopram

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acler et al. (2009)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=NA</td>
<td>N=20</td>
<td>20 patients with unilateral stroke were randomized to receive 10 mg/day of citalopram or a placebo in combination with physiotherapy, which was initiated within 10 days following stroke. Antidepressant treatment lasted for 4 months. Stroke severity, assessed using NIHSS, Barthel</td>
</tr>
</tbody>
</table>
Index and depression (Beck Depression Inventory and Hamilton Depressive Rating Scale) were tested before (T1) and 1 month after (T2) beginning drug treatment. Hemisphere was significantly higher in the experimental group compared to the control group.

**Gourab et al. (2015)**
USA
RCT crossover
PEDro=7
TPSmean=9.1±7.6yr
Nstart=11
Nend=10

**Population:** Mean age=57±10yr; Gender: Males=7, Females=3.
**Intervention:** Participants either received a single 10mg dose of escitalopram or placebo. The individuals that received escitalopram first then received the placebo a week later, and the placebo first received escitalopram. Assessments were done before each dose and also 5 hours after each dose.
**Outcomes:** 6 Minute Walk Test (6MWT); maximum gait velocity; Fugl-Meyer Assessment for the lower extremity (FMA-LE).

There were no significant differences in 6MWT, maximum gait velocity, or FMA-LE.

**Table 9.10.3.2 Summary of Studies Evaluating Fluoxetine**

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dam et al. (1996) USA</td>
<td>RCT PEDro=5 TPS&lt;1-6mo</td>
<td>N=52</td>
<td>52 severely disabled hemiplegic subjects were randomly assigned to three treatment groups; during 3 months of physical therapy, patients were treated with placebo, maprotiline (150 mg/d), or fluoxetine (20 mg/d). Outcomes assess before and after treatment included the Barthel Index, degree of neurological deficit by a neurological scale for hemiplegic subjects, and depressive symptomatology by the Hamilton Depression Rating Scale. The diverse treatments ameliorated walking and activities of daily living capacities to different extents. The greatest improvements were observed in the fluoxetine-treated group and the lowest in the maprotiline-treated group. Furthermore, fluoxetine yielded a significantly larger number of patients with good recovery compared with maprotiline or placebo. These effects of the drugs were not related to their efficacy in treating depressive symptoms.</td>
<td></td>
</tr>
<tr>
<td>Robinson et al. (2000) USA</td>
<td>RCT PEDro=8 TPS&lt;6mo</td>
<td>N=104</td>
<td>104 patients with stroke onset of less than 6 months were randomized to receive nortriptyline (max 100 mg/d), fluoxetine (max 40 mg/d) or placebo over 12 weeks of treatment. Both depressed and nondepressed patients were enrolled to determine whether improved recovery could be mediated by mechanisms unrelated to depression. Response to treatment of depression for individual patients was defined as a greater-than-50% reduction in scores on the Hamilton Rating Scale for Depression and no longer fulfilling diagnostic criteria for major or minor depression. Functional recovery was assessed using FIM, assessed before and after treatment. Among patients who were depressed at study entry, those treated with nortriptyline had higher FIM scores compared with those treated with placebo or fluoxetine. Nortriptyline also produced a significantly higher response rate than fluoxetine or placebo in treating poststroke depression and anxiety. Among non-depressed patients, there was no difference in the FIM score among study groups.</td>
<td></td>
</tr>
</tbody>
</table>
| Fruehwald et al. (2003) Austria | RCT PEDro=9 | 54 patients suffering from moderate to severe post-stroke depression were randomized within 2 weeks of stroke to either treatment with fluoxetine or to placebo control. Treatment lasted | Significant improvement was seen in both groups within 4 weeks; however no advantage of fluoxetine was noted at this time. There were no differences between groups in BI or SSS scores at }
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TPS<2wk
N=54

for 12 weeks. Outcomes assessed at baseline, 1, 3 and 18 months included Scandinavian Stroke Scale, BI and Rankin Scale.

18 months.

Mikami et al. (2011) Japan RCT PEDro=8 TPS<6mo N=83

1-year follow-up to Robinson et al. (2000). Comparison between patients who were administered antidepressants for 3 months compared to patients given placebo for 3 months.

Patients who received fluoxetine or nortriptyline had significantly greater improvement in modified Rankin Scale scores compared to patients who received placebo after controlling for potential confounders including age, intensity of rehabilitation therapy, baseline stroke severity, and baseline Hamilton Depression Rating Scale (p = 0.002). There were no significant differences in FIM scores between groups.

Chollet et al. (2011) France RCT PEDro=9 TPS=5-10d N=118

118 patients free from clinical depression and not taking any anti-depressant medication enrolled within 5 to 10 days of stroke with Fugl-Meyer (FM) scores of <55 were randomized to receive fluoxetine (20 mg/day for 90 days) (n=57) or placebo (n=56) in addition to routine physiotherapy. The primary outcome was the change in FM scores at day 90.

Mean FM total and lower limb subscores were significantly higher in the fluoxetine group compared with control (54 vs 35, p<0.01 and 24 vs. 19, p=0.001) Change in FM scores was also higher in the fluoxetine group. The incidence of depression was significantly lower in the fluoxetine group (7% vs. 29%, p=0.002).

Shah (2016) Iran RCT PEDro=8 TPS=5-10d N=89

Patients were randomized to receive fluoxetine (20mg; n=45) or placebo (n=44) daily for 3mo.

At 3mo, mean improvement on the Fugl-Meyer Motor Scale was significantly greater in the fluoxetine group than placebo group (35.64 vs 23.60, p=0.001).

9.10.4 Other Medications

Table 9.10.4.1 Summary of Studies Evaluating Other Medications

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simpson et al. (2015) USA</td>
<td>RCT crossover</td>
<td>PEDro=5</td>
<td>TPS1:53.1±9.22mo TPS2:43.1±6.42mo Nstart=83 Nend=70</td>
<td>Population: Group 1 (G1, N=55): Mean age=57.5±1.31yr; Gender: Males=37, Females=18. Group 2 (G2; N=28): Mean age=63.5±1.68yr; Gender: Males=18, Females=10.</td>
<td>1. 54.5% of participants reported ≥ 1 TEAE while on D-ER compared with 37% on placebo. Most TEAEs were mild (38% in D-ER, 20% in placebo) or moderate (13% D-ER, 16% placebo). Two participants however did discontinue the study during D-ER treatment because of general malaise and lower extremity weakness. Most common TEAEs were dizziness, nausea, fatigue, insomnia, and arthralgia. 2. There was an overall change in walking speed of the 25FWT favouring D-ER use over the placebo (0.027).</td>
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</table>
### Chang et al. (2016)

Korea  
RCT  
PEDro=6  
TPS<7d  
N_{start}=70  
N_{end}=66  

**Population**: Experimental Group (EG; N=34): Mean age=64.7±10.1yr; Gender: Males=29, Females=5.  
Control Group (CG; N=32): Mean age=63.0±10.6yr;  
Gender: Males=24, Females=8.  

**Intervention**: Rehabilitation program consisted of 2hr physical therapy and 1hr of occupational therapy. EG received 30mL cerebrolysin, CG received placebo. Treatment was 21d. Assessments were performed at baseline (T0), post intervention (T1), 2mo (T2), and 3mo (T3).  

**Outcomes**: Fugl-Meyer Assessment total score (FMA-T); FMA upper limb (FMA-UL); FMA lower limb (FMA-LL).  

1. The EG did significantly better than the CG on the FMA-T, and FMA-UL at T2 and T3 (p<0.05).  
2. There were no significant interactions between groups on the FMA-LL.

### Di Cesare et al. (2016)

Multinational  
RCT  
PEDro=6  
TPS_{A1}=61.0±12.1hr  
TPS_{A2}=59.4±9.8hr  
TPS_{E1}=60.6±9.6hr  
TPS_{E2}=63.6±11.5hr  
TPS_{E3}=61.5±13.0hr  
TPS_{P1}=59.4±11.7hr  
N_{start}=139  
N_{end}=137  

**Population**: Experimental Group 1 (EG1; N=11): Mean age=62.3±14.3yr; Gender: Males=7, Females=4.  
Placebo 1 (P1; N=9): Mean age=64.7±6.0yr; Gender: Males=7, Females=2.  
Experimental Group 2 (EG2; N=11): Mean age=69.8±8.3yr; Gender: Males=4, Females=7.  
Placebo 2 (P2; N=10): Mean age=65.8±13.4yr; Gender: Males=7, Females=3.  
Experimental Group 3 (EG3; N=70): Mean age=64.2±13.1yr; Gender: Males=42, Females=28.  
Placebo 3 (P3; N=67): Mean age=65.6±11.3yr; Gender: Males=41, Females=26.  

**Intervention**: In part one of the study, participants underwent 90 days of 1, 3, and 6mg PF-3049423 daily in EG1, EG2 and EG3 respectively. In part 2, EG3 was used to evaluate the effectiveness of the treatment compared to a placebo. EG3 was the main group used for comparison with the placebo groups, and assessments were done at baseline and post-intervention.  

**Outcomes**: Modified Rankin Scale (mRS); Barthel Index (BI); National Institutes of Health Stroke Scale (NIHSS); Box and Block Tests (BBT); Hand-Grip Strength test; 10 Meter Walk Test (10MWT); RBANS Coding and Naming Subtests; Line Cancellation Test; and Recognition Memory Test.  

1. There was no significant difference between the EG3 and the placebo groups (P1, P2, P3) on the mRS. The proportion of subject with an mRS score of 2 or higher at 90d was 42.6% in EG3 and 46.2% in the combined placebo groups (P1, P2, P3).  
2. There was no difference between EG3 and the placebo groups on the BI, NIHSS, BBT, hand grip strength test, 10MWT, RBANS Coding and Naming Subtests, Line Cancellation Test, or Recognition Memory Test.

## 9.11 Spasticity and Contractures

### 9.11.1 Contracture Prevention

#### Table 9.11.1 Contracture Prevention

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Robinson et al. (2008)</td>
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<td>30 non-ambulatory rehabilitation patients were used</td>
<td>From week 0 to 10, the night splint group had</td>
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9. Mobility and the Lower Extremity  

[www.ebrsr.com](http://www.ebrsr.com)
randomized to one of 2 groups. For four weeks, one group wore a splint with the affected ankle at plantar grade, 7 nights per week, while the other group stood on a tilt table for 30 min with the ankle at maximum dorsiflexion, 5 times per week. This was followed by a period of no intervention for six weeks. Both groups received inpatient and outpatient rehabilitation emphasising mobility. The primary outcome was contracture measured as maximum passive ankle dorsiflexion, measured at baseline, 4 and 10 weeks. lost 2.4 degrees, whereas the tilt table group had lost 5.9 degrees. The night splint group had the same amount of ankle dorsiflexion as the tilt table group by Week 4 (mean difference 1 deg, 95% CI -5 to 7), and by Week 10 (mean difference 3.5 deg, 95% CI -3 to 10).

9.11.2 Botulinum Toxin

Table 9.11.2.1 Summary of Studies Evaluating Botulinum Toxin

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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<tr>
<td>vs Placebo</td>
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<td><strong>Burbaud et al. (1996)</strong></td>
<td>France</td>
<td>RCT PEDro=7 TPS=NA N=23</td>
<td>In a double-blinded, placebo-controlled trial, 23 adult hemiparetic stroke patients with ankle plantar flexor and foot invertor spasticity received 1 injection of botulinum toxin (BTX) and one of placebo in random, one at day 0 and the other at day 90. Patients were examined at day 0, 30, 90 and 120. Patients were assessed on the Ashworth scale, Fugl-Meyer Scale, gait velocity and a self-report of treatment efficacy.</td>
<td>Patients reported subject improvement in foot spasticity after BTX but not after placebo injection. Significant changes noted on the Ashworth scale values for ankle extensors and invertors and for active dorsiflexion after BTX injection. BTX was less effective in patients with longer duration of spasticity.</td>
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<td><strong>Pittock et al. (2003)</strong></td>
<td>RCT PEDro=8 TPS=NA N=234</td>
<td>In a double-blind, placebo-controlled, dose-ranging study, 234 patients with hemiparesis with spastic equinovarus deformity of the ankle after stroke were randomized to one of 4 treatment groups: 500 units of Dysport; 1000 units of Dysport; 1500 units of Dysport and placebo. Patients were assessed on the Ashworth scale, Fugl-Meyer Scale, gait velocity and a self-report of treatment efficacy.</td>
<td>Distance covered during 2-minute walking test significantly increased in each group, but there were no differences between groups. Significant improvement in calf spasticity, limp pain reduction in use of walking was noted in the Dysport groups relative to the control group.</td>
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<td><strong>Kaji et al. (2010)</strong></td>
<td>Japan</td>
<td>RCT PEDro=9 TPS&lt;6mo N=120</td>
<td>120 patients from 19 medical institutions with lower limb spasticity following stroke &gt; 6 months previously were randomized to a single treatment of 300 U BoNTA or placebo. Assessments were conducted bi-weekly from baseline to 12 weeks following treatment and included MAS of the ankle flexor, gait pattern scale using the Physician Rating Scale (-1 to 9/limb), Gait speed (10-m timed walk) and clinical global impression (-5 to +5).</td>
<td>There was a significant mean reduction in MAS scores at weeks 4, 6 and 8 in the treatment group compared with the control group; however, there were no significant differences between groups at week 10 or 12. Significant improvement in the Clinicians Global Impression was noted by the investigator at weeks 4, 6 and 8 (p = 0.016-0.048), but not by the patient or physical/occupational therapist. There were no other significant differences between groups.</td>
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<td><strong>Dunne et al. (2012)</strong></td>
<td>RCT PEDro=7 TPS≥6wk</td>
<td>85 stroke patients (≥ 6 weeks post stroke), with lower extremity hypertonia received (a) 200U onabotulinumtoxinA (n=28) (b)300U onabotulinumtoxinA (n=28) or (c) saline injections</td>
<td>No significant differences were seen between the two groups receiving botox so data was pooled for those groups. There was no significant difference reported</td>
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</table>
**N=85**
to the the tibialis posterior, soleus and flexor digitorum longus or medial gastrocnemius. Assessments were conducted at 4, 8, 12 and 16 weeks post injection and included primary outcomes of adverse event incidence and MAS of ankle plantarflexors. Secondary outcomes included self reported spasm frequency and physician rated hypertonia (7 point likert scale).

**between treatment and placebo groups on primary outcome measures. Significantly more patients in the intervention group reported reduction in leg spasms (22/26 vs 4/19, p=0.01), improvement ≥1 point in the physician rating for hypertonia (29/54 vs 8/29, p=0.04), better gait quality than baseline (17/54 vs 6/29, p=0.02), increase in ankle dorsiflexion ≥5° (8/54 vs 1/29, p=0.03) and improvement in pain from baseline (8/14 vs 1/8, p=0.02).

### Tok et al. (2012)
**Turkey**  
**PCT**  
**No Score**  
**TPS=Chronic**  
**N=25**
25 stroke patients (≥6 months post stroke) presenting with stiff knee gait received either a) 100-125U of onabotulinumtoxinA (n=15) or b) placebo (n=10) injected into the rectus femoris muscle. MAS assessments were conducted at baseline and 8 weeks post injection.

In comparison to the placebo group (2.30±0.82), those receiving onabotulinumtoxinA (1.40±0.50) significantly improved rectus femorius spasticity at 8 weeks post injection (p<0.007).

### Fietzek et al. (2014)
**Germany**  
**RCT**  
**PEDro=7**  
**Blinded phase (BP)**

| TPSGroup1 | 71.1d |
| NStart | 52 |
| NEnd | 52 |

**Open label phase (OLP)**

| TPSGroup1 | 64.5d |
| NStart | 52 |
| NEnd | 26 |

**Population:** First treatment cycle (BP)  
Group 1 (N=26): Mean age=54.5±13.9yr; Gender: Males=13, Females=13. Group 2 (N=26): Mean age=54.2±14.1yr; Gender: Males=17, Females=9.  

**Second treatment cycle (OLP)**  
Group 1 (N=11): Mean age=49.1±16.2yr; Gender: Males=5, Females=6. Group 2 (N=15): Mean age=58.2±13.7yr; Gender: Males=10, Females=5.

**Intervention:** Participants were randomly assigned to group 1 and received 2 BoNT/A injections into 4 calf muscles, or to group 2 and received a saline injection first, followed up with a BoNT/A injection. For the first treatment cycle (RCT) patients each received the first injection (either BoNT/A or saline) at week 0 and followed up at week 4 and week 12. For the second treatment cycle (Open label phase) BoNT/A injections were administered to both groups at week 12, and the participants were followed up at week 16, 24, and 36. All patients also received conventional therapy.

**Outcomes:** modified Ashworth scale (MAS).

### Ward et al. (2014)
**Canada, Germany, UK, Sweden**  
**RCT**  
**PEDro=7**  
**Med TPS=24.0mo**  
**Med TPS=21.2mo**

| NStart | 274 |
| NEnd | 273 |

**Population:** Treatment group (TG; N=139): Median age (range)=64.1yr (22.6-81.2); Gender: Males=85, Females=54. Placebo group (PG; N=135): Median age (range)=61.8yr (26.8-82.4); Gender: Males=76, Females=59.

**Intervention:** Participants were randomly either allocated to the treatment group and received OnabotulinumtoxinA injection(s) and standard care (SC), or to the placebo group and received placebo injection(s) and SC, for the RCT portion of the study. At week 12 a second dose of injection was administered. Participants were followed up for 52 weeks.

**Outcomes:** Goal attainment scaling (GAS) including

| 1. There was no significant difference in the principal active functional goal achievement, secondary functional goal achievement (both passive and active), and secondary active functional goal achievement between the TG and the PG at week 12, week 21/10 after second injection, and at 52 weeks.  
2. The TG showed a greater secondary passive functional goal achievement compared to the PG at week 24/10 after the second injection (p=0.016).  
3. The mean REPAS scores were significantly reduced at 24 weeks, or 10 weeks after the second injection. |
passive and active functional goals for upper limb and lower limb; Resistance to passive movement (REPAS).

4. For upper limb principal active functional goals, statistically significant highflyer GAS scores were attained by the treatment group compared to the placebo group (p=0.034).


**Population:** Treatment group (TG; N=11): Mean age=55±12yr; Gender: Males=7, Females=4. Control Group (CG; N=12): Mean age=58±14yr; Gender: Males=8, Females=4.

**Intervention:** Participants were randomly assigned to either the EG and received 200 units of botulinum toxin type A (BTX-A) in the gastrocnemius and the posterior tibial muscle, or to the CG and received the same amount of placebo injection in the same muscles as in the treatment group. Both groups received conventional rehabilitation. Assessments were carried out at baseline (week 0), 4, and 8 weeks after the injections.

**Outcomes:** Fugl-Meyer assessment (FMA); modified Ashworth Scale (MAS); Modified Barthel Index (MBI), surface electromyography (sEMG); step length; cadence; gait speed; 6 minute walking distance (6MWT).

1. The gait analysis, FMA, and MBI results were significantly improved in both groups (p<0.05).
2. The FMA and the MBI scores by week 8 were significantly better in the treatment groups than those in the CG (all p<0.05).
3. A significant reduction in sEMG levels of gastrocnemius activity was found in the TG (p<0.05). The sEMG levels between TG and CG at week 4 and week 8 were found to be significant (all p<0.05).
4. The step length, cadence, speed and the 6MWT of the TG were significantly greater than those in the CG (all p<0.05).
5. At week 8, the MAS scores in the TG were significantly lower than those in the CG (p<0.05).

Wissel et al. (2016) Germany RCT PEDro=8 TPS=47(3-256)mo TPS=46(3-408)mo N_start=273 N_end=273

**Population:** Experimental Group (EG; N=139): Mean age=62yr; Gender: Males=85, Females=54. Control Group (CG; N=134): Mean age=61yr; Gender: Males=75, Females=59.

**Intervention:** Participants with post-stroke spasticity and pain were randomized to receive onabotulinumtoxinA and standard care, or to receive placebo injection and standard care. The intervention was double-blinded for 22 to 34 weeks, and a second phase open-label was provided for 52 weeks. Assessments were conducted at baseline, week 12, end of the double-blind treatment, and at week 52.

**Outcomes:** Pain numeric rating scale (PNRS); proportion of participants with baseline pain >4 achieving 30% and 50% improvement in pain; Goal Attainment Scale (GAS).

Double-blind phase:
1. At 12wk, the mean reduction in PNRS from baseline was greater in the EG than the CG (p<0.05).
2. At 24wk (end of treatment), the EG had lower pain recorded by the PNRS compared to the CG (p<0.05).
3. In the pain subgroup, more patients in the EG achieved clinically meaningful reduction in pain relative to the CG at 12wk in both the 30% reduction (p<0.05), and 50% reduction (p<0.05). At 24wk, more participants in the EG group reported a 30% reduction in pain relative to the CG (p<0.05).
4. There were no significant differences between groups for the overall GAS at 12wk and 24wk. The upper limb and lower limb subscales of the GAS were also not significantly different between the two groups at any of the time points.

vs Devices

Reiter et al. (1998) Italy RCT PEDro=5 TPS=22(10-72)mo N=18

Single blind trial of 18 patients randomized to receive either EMG-guided injection of 190 to 320U of BTA diluted with saline to a concentration of 5U/0.1mL in 3 to 5 muscles (group A) or to receive a fixed doses or 100U of BTA into two points of tibialis posterior muscle alone followed by ankle-foot taping (group B).

Group A showed greater gains in dorsiflexion at rest and after passive mobilization. Benefits of treatment persisted in 7 group A patients at 3 months whereas it vanished in 6 group B patients. Gait velocity showed an average increase of 17% in group A and 23 % in group B. Step length increased by an average of 21% in group A and
<table>
<thead>
<tr>
<th>Authors</th>
<th>Study Design</th>
<th>Country</th>
<th>PEDro Score</th>
<th>TPS Duration</th>
<th>Sample Size</th>
<th>Number of Treatments</th>
<th>Treatment Description</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Farina et al. (2007)</td>
<td>RCT</td>
<td>Italy</td>
<td>5</td>
<td>6-24 mo</td>
<td>N=13</td>
<td></td>
<td>13 stroke patients with equinovarus foot were randomized to receive a single injection of botulinum toxin A (BTA) injection plus ankle-foot casting (n=6) or BTA alone (n=7). The tibialis posterior and calf muscles (range of BTA injection: 190 to 320 U) were treated in each patient. Rigid, customized castings were worn at night for four months. Each patient was examined before, and at two and four months after BTA injection. Outcomes included the Modified Ashworth Scale and the 10-meter walking test.</td>
<td>At four months, the mean MAS scores were lower for patients in the BTA+casting group compared with control (-0.25 vs. 0.43, p&lt;0.05). There were no significant differences in the 10 m walking test at either 2 or 4 mos following treatment.</td>
</tr>
<tr>
<td>Karadag-Saygi et al. (2010)</td>
<td>RCT</td>
<td>Turkey</td>
<td>7</td>
<td>&gt;6 mo</td>
<td>N=20</td>
<td></td>
<td>20 subjects &gt;6 months following stroke with mRS scores of 2-4, able to walk 10 m with or without assistance were randomized to receive a single injection of Botox (75-100 U per muscle head) + sham taping or the same dose of Botox + taping using the kinesiotaping method. Patients in both groups also received home-based range of motion and stretching exercises. Outcomes were assessed before treatment, at 2 weeks and 1,3 and 6 months. Outcomes included MAS, gait speed and step length.</td>
<td>Patients in both groups improved, but at 6 months following treatment there were no significant differences between groups on any of the outcomes.</td>
</tr>
<tr>
<td>Carda et al. (2011)</td>
<td>RCT</td>
<td>Italy</td>
<td>6</td>
<td>Chronic</td>
<td>N=69</td>
<td></td>
<td>69 chronic hemiplegic adult patients with spastic equinus foot received 100 U of botulinum toxin type A injection at the plantar flexors. Patients were then randomly assigned to three groups and treated with either taping, casting or stretching for one week, and with stretching and gait training for the next week. Outcomes included Modified Ashworth Scale MAS), six-minute walking test (6MWT), 10-metre walking test, Functional Ambulation Categories and were assessed before treatment, at 20 days and 90 days following treatment.</td>
<td>At 90 days following treatment the mean MAS scores for the taping, casting and stretching groups were 2.8, 1.5 and 3.5, (p&lt;0.05) respectively. The difference in means scores was significantly lower in the casting group compared with the stretching group. The same pattern was observed for the 6MWT. At 90 days the mean distance walked was higher among patients in the casting group compared with those in the stretching group (245 vs. 197, p&lt;0.02). There were no other significant differences in any of the other outcomes among groups.</td>
</tr>
<tr>
<td>Ding et al. (2015)</td>
<td>RCT</td>
<td>China</td>
<td>6</td>
<td>(Unspecified time)</td>
<td>N=103</td>
<td></td>
<td>Population: Control Group (CG; N=33): Mean age=64.2±12.3y; Gender: Males=15, Females=18. Observation Group (OG; N=35): Mean age=62.7±11.5y; Gender: Males=16, Females=19. Experimental Group (EG; N=35): Mean age=63.4±10.1y; Gender: Males=18, Females=17. Intervention: Participants were randomly allocated to three groups: control, observation, and treatment. The CG received conventional rehabilitation, the observation group received conventional rehabilitation and Botulinum Toxin A (BTA) injections, and the EG received the same treatment as the OG along with an ankle foot brace. Participants were assessed before treatment, in the first month, the third month, and 6 mo after the intervention.</td>
<td>1. The CG demonstrated a significant change from before treatment to 3 and 6 mo after treatment on the CSI (all p&lt;0.05), BBS (all p&lt;0.05), FMA (all p&lt;0.05), and FIM (all p&lt;0.05). 2. The OG showed a significant change from before treatment to 1, 3 and 6 mo after treatment on the CSI (all p&lt;0.05), BBS (all p&lt;0.05), FMA (all p&lt;0.05), and on the FIM (all p&lt;0.05). 3. The EG showed a significant change from before treatment to 1, 3, and 6 mo after treatment on the CSI (all p&lt;0.05), BBS (all p&lt;0.05), FMA (all p&lt;0.05) and on the FIM (all p&lt;0.05). 4. There were no other significant differences</td>
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<tr>
<td>Outcomes:</td>
<td>Clinic spasticity influx (CSI); Fugl-Meyer Assessment (FMA); Berg balance scale (BBS); Functional independence measure (FIM).</td>
<td>between the observation and the CGs (p&gt;0.05).</td>
<td>Significant differences were found between the 3 groups at 3 and 6 mo after treatment on the CIS, BBS, FMA, and FIM (all p&lt;0.05).</td>
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<tr>
<td>Bayram et al. (2006)</td>
<td>Turkey RCT PEDro=6 TPS=Chronic N=12</td>
<td>12 chronic stroke patients with spastic drop foot were randomly assigned to receive low-dose (100 units) botulinum toxin (BT) injection to the posterior tibial muscle in combination with short-term electrical stimulation (n = 6) or high dose BT injections in equal doses to the posterior tibial, soleus, medial, and lateral gastrocnemius muscles (n=6). Evaluations included resting position angle, active and passive ankle range of motion, Modified Ashworth Scale, time walking 10 m, clonus score, Brace Wear Scale, and Global Assessment of Spasticity Scale and were conducted at baseline and 2, 4, 8, and 12 wks after the treatment.</td>
<td>No significant difference was found between the study groups after treatment. There was significant within group Improvement in all study parameters in both groups. Improvement in spasticity following high dose BT treatment was maintained for a longer period of time; however, functional improvement and patient satisfaction were sustained until the end of the study in both groups.</td>
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<td>Baricich et al. (2008)</td>
<td>Italy RCT PEDro=5 TPS=Chronic N=24</td>
<td>24 chronic stroke patients received 500 IU of Dysport into the gastrocnemius muscle and were then randomized to one of 3 additional therapy groups: taping (maintained for 5 days), electrical stimulation (30 min, 5x/week) or stretching (30 min x 7 days). Subjects were evaluated before treatment (t0), and at 10 (t1), 20 (t2) and 90 (t3) days after treatment. Outcome measures were: Modified Ashworth Scale (MAS); passive range of motion (PROM) at the ankle; measurement of muscle action potential at the gastrocnemius medialis; and measurement of maximum ankle dorsiflexion angle in stance.</td>
<td>Mean MAS scores were lowest in the ES group at t1. The taping and electrical stimulation groups performed better in all outcome measures at t3. The taping group performed better mainly for maximum ankle dorsiflexion angle in stance. The stretching group showed a less durable result, with some worsening at the t3 evaluation compared with the assessment performed before treatment.</td>
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<td>Picelli et al. (2014)</td>
<td>Italy RCT PEDro=8 TPS=US=3.8yr TPS=TENS=3.9yr TPS=BoNT-A=4.6yr NStart=30 NEnd=30</td>
<td>Population: Therapeutic ultrasound (US; N=10): Mean age=64.2±8.7yr; Gender: Males=6, Females=4. Transcutaneous electrical nerve stimulation (TENS; N=10): Mean age: 62.7±12.9yr; Gender: Males=5, Females=5. Botulinum toxin type A (BoNT-A; N=10): Mean age=65.2±5.5yr; Gender: Males=8, Females=2. Intervention: Participants were randomly allocated one of three treatment groups. In one group, participants received therapeutic ultrasound (US) to the affected leg calf muscles (for 10 minutes, 5 days a week for 2 weeks), in the second group participants received transcutaneous electrical nerve stimulation (TENS) (for 15 minutes, 5 days a week, for 2 weeks), and in the third group participants received 200 units of botulinum toxin type A to the gastrocnemius muscle belly on the affected side. Participants were assessed on the first day of treatment (immediately before the administration of intervention) (T0), at 15 days</td>
<td>1. MAS significantly differed between groups at T2 (p=0.002), and T3 (p=0.005), as well as the ankle PROM at T1 (p=0.001), T2 (p&lt;0.001), and T3 (p&lt;0.001). 2. Patients in the BoNT-A group performed significantly better than those in the US group in the MAS at T2 (p=0.002, effect size=0.69) and T3 (p=0.006, effect size=0.60), as well as in the ankle PROM at T1 (p=0.002, effect size=-0.68), at T2 (p=0.002, effect size=-0.69), and T3 (p=0.002, effect size=-0.69). 3. Patients in the BoNT-A group performed significantly better than those in the TENS group in the MAS at T2 (p=0.003, effect size=0.65) and T3 (p=0.006, effect size=0.60), as well as in the ankle PROM at T1 (p=0.001, effect size=-0.76), T2 (p&lt;0.001, effect size=-0.82), and T3 (p&lt;0.001, effect size=0.85).</td>
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</table>
(T1), 30 days (T2) ad at 90 days (T3) after the first clinical evaluation.

**Outcomes:** Passive range of motion (PROM); modified Ashworth Scale (MAS).

4. No significant differences were found between patients in the US and TENS groups in all outcome measures at posttreatment evaluations.

5. Only patients in the BoNT-A group demonstrated a significant difference compared to baseline on the MAS and ankle PROM at T1 (MAS: $p=0.008$; PROM: $p=0.004$), T2 (MAS: $p=0.004$; PROM: $p=0.004$), and at T3 (MAS: $p=0.005$; PROM: $p=0.004$).

6. The TENS group demonstrated a significant change from baseline on the MAS at T1 only ($p=0.014$, CI=[-0.96,-0.23]).

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<table>
<thead>
<tr>
<th>vs Antiseptic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Kirazli et al.</strong> (1998) Turkey RCT PEDro=8 TPS&gt;6mo N=20</td>
</tr>
<tr>
<td>Double blind trial of 20 patients randomized to receive either 400 units of botulinum toxin Type A into the calf muscles or to receive a tibial nerve blockage with 3 ml of 5% phenol.</td>
</tr>
<tr>
<td>Significant improvement for dorsiflexion and eversion for BTX-A observed at week 2 and 4. Significantly better Global Assessment scores at weeks 2, 4, 6, 8 for BTX-A but no significant difference between groups at week 12.</td>
</tr>
</tbody>
</table>

<p>| <strong>Bollens et al.</strong> (2013) Belgium RCT PEDro=8 TPSWWN:2.5yr TPSBTX:3.5yr NStart=16 NEnd=16 |
| Population: Tibial Nerve Neurotomy (TNN; N=8): Mean age=49.8yr; Gender: Males=3, Females=5. Botulinum Toxin (BTX; N=8): Mean age=52.3yr; Gender: Males=4, Females=4. |
| Intervention: Participants were randomly allocated to receive tibial nerve neurotomy (TNN) treatment to the soleus nerve, tibialis posterior, and the flexor hallucis longus, or to receive Botulinum Toxin injections in the same muscles as in the previous group. Participants were assessed before the treatment (T0), at 2 mo (T1), and at 6 mo (T2) after the treatment. |
| <strong>Outcomes:</strong> modified Ashworth Scale (MAS); passive range of motion (PROM) of ankle; Stroke impairment assessment set (SIAS); 10-m walk test (10MWT); Functional walking category (FWC); Functional ambulation categories (FAC); Stratification in participation (SAPS-STROKE); Norm-based scoring (NBS); 36 item short-form Health survey (36-SF); Tardieu scale; Medical Research Council (MRC). |
| 1. In the TNN group, the L-path significantly decreased from T0 to T1 ($p&lt;0.05$). |
| 2. The improvement from T0 to T1 was found to be significantly greater in the TNN group compared to the BTX group on the MAS scores of the soleus ($p=0.001$), and on the scores of the tardieu soleus ($p=0.007$). The improvement in the MAS scores of the soleus were also maintained from T0 to T2 ($p=0.021$). |
| 3. The mean difference between T1 and T0 was also significantly different between groups, with the TNN group demonstrating greater improvement on the SIAS ($p=0.028$). This improvement was found to be significantly different from T0 to T2 as well ($p=0.003$). |
| 4. There was no significant difference between the two groups at various time points regarding the PROM and MRC scores. |
| 5. A significant time effect was found regarding the ankle kinematics for the maximal dorsal flexion of the ankle in stance phase ($p=0.028$) and for the maximal dorsal flexion of the ankle in swing phase ($p=0.034$). |
| 6. No specific effect of time or treatment was found on the 10MWT, knee kinematics, ankle joint momentum, ABILOCO, SATISPART-Stroke, and SF-36. |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Intervention</th>
<th>Outcome Measures</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Childers et al. (1996)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Chronic</td>
<td>N=17</td>
<td>Double blind trial of 17 patients randomized to either Group 1 receiving BTX-A at mid belly of the gastrocnemius or to Group 2 receiving BTX-A at the proximal portion of muscle located distal to the popliteal fossa. A placebo was injected at the alternative site in both groups.</td>
<td>No significant differences were noted between the two treatments on any of the outcome measures.</td>
<td></td>
</tr>
<tr>
<td>Picelli et al. (2012)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS≥6mo</td>
<td>N=56</td>
<td>56 stroke patients (≥6 months post stroke), with spastic equinus foot received 250U of onabotulinumtoxinA injected into the gastrocnemius medialis and 250U onabotulinumtoxinA in the gastrocnemius lateralis. Assessments were conducted at baseline and 4 weeks post injection; primary outcome measures included MAS, Tardieu Scale, and ankle passive range of motion.</td>
<td>MAS scores (p&lt;0.001), Tardieu Scale scores (p&lt;0.001), and ankle passive range of motion (p&lt;0.001) improved by week 4 follow-up.</td>
<td></td>
</tr>
<tr>
<td>Im et al. (2014)</td>
<td>Korea</td>
<td>RCT</td>
<td>PEDro=9</td>
<td>TPS=277 (105-718)d</td>
<td>TPS=233 (68-649)d</td>
<td>Population: Experimental Group 1 (EG1; N=21): Median age (range)=47 (20.2-69.0)yr; Gender: Males=14, Females=7. Experimental Group 2 (EG2; N=17): Median age (range)=49 (30.0-56.0)yr; Gender: Males=13, Females=4. Intervention: Both the EG1 and EG2 groups’ total calf length between the popliteal crease and the bimalleolar line was measured. The EG1 group received 200 U of botulinum toxin type A (BTX-A) at 2/10 of the calf length and at the midpoint between 2/10 and 3/10 of the calf length. The EG2 group received 200 U BTX-A at and below the mid-belly of the gastrocnemius. Assessments were conducted at baseline (T0) and at 8wks (T1). Outcome: Modified Tardieu Scale (MTS); Joint Angle (JA); Angle of Catch at Fast Velocity Stretch (ACFVS); Angle from Passive Range of Motion at Slow Velocity Stretch (APRoM); Clonus Scale (CS); Modified Ashworth Scale (MAS); 10 Meter Walk Test (10MWT); Locomotion Ability for Adults with Lower Limb Impairments Assessment (ABILOCO); Functional Ambulatory Category (FAC).</td>
<td>No significant differences between EG1 and EG2 were found on any of the measures.</td>
<td></td>
</tr>
<tr>
<td>Mancini et al. (2005)</td>
<td>Italy</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Chronic</td>
<td>N=45</td>
<td>45 patients with chronic stroke and lower-limb spasticity were randomized to receive one of 3 injection of Botox: i) low dose, ii) medium dose and iii) high dose. Evaluations included Modified Ashworth Scale, Medical Research Council Scale and gait velocity, as well as a visual analogue scale (VAS) for gait function and pain and were conducted at baseline, week 4 and 4 months.</td>
<td>Groups 1, 2 and 3 received a total Botox dose of 167 U, 322 U and 540 U, respectively. All groups had improved by 4 weeks, but patients in groups 2 and 3 only retained the beneficial effects. Patients in group 3 reported more adverse effects.</td>
<td></td>
</tr>
<tr>
<td>Pimentel et al. (2014)</td>
<td>Brazil</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=41.6±63.4mo</td>
<td>TPS=34.5±33.8mo</td>
<td>Population: Experimental Group 1 (EG1; N=11): Mean age=50.5±6.8yr; Gender: Males=4, Females=7. Experimental Group 2 (EG2; N=10): Mean age=47.9±3.8yr; Gender: Males=6, Females=4. Intervention: EG1 received a total of 300 U of Botox.</td>
<td>1. There were no significant differences between EG1 and EG2 for 10MWT or mFIM. 2. MAS was significantly different between the two groups at T3 and T4, with significant improvement in EG1 (p=0.012; p=0.0001).</td>
<td></td>
</tr>
</tbody>
</table>
N<sub>Start</sub>=26  
N<sub>End</sub>=21

<table>
<thead>
<tr>
<th>Author, Year Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beckerman et al. (1996) Netherlands RCT PEDro=8 TPS&lt;sub&gt;Median&lt;/sub&gt;=34mo N=60</td>
<td>Single blind, placebo control trial of 60 patients randomized to 1 of 4 treatment groups: Thermocoagulation (TH) of peripheral nerves with a custom made ankle foot orthosis (AFO) in five degrees of dorsiflexion (Group 1); Placebo thermocoagulation (PTH) with the radiofrequency energy output zero with AFO (Group 2); TH with a placebo AFO with free range motion of dorsiflexion (PAFO) (Group 3); and PTH with PAFO (Group 4).</td>
<td>Reduced spasticity found in 35% of patients with TH compared to 10% of the PTH patients. Significantly greater proportion of Groups 1 and 3 (both TH) patients showed marked improvement in Achilles tendon reflexes and ankle clonus than groups 2 and 4 (both PTH).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kirazli et al. (1998) Turkey RCT PEDro=8 TPS&lt;sub&gt;6mo&lt;/sub&gt;=20</td>
<td>Double blind trial of 20 patients randomized to receive either 400 units of botulinum toxin Type A into the calf muscles or to receive a tibial nerve blockage with 3 ml of 5% phenol.</td>
<td>Significant improvement for dorsiflexion and eversion for BTX-A observed at week 2 and 4. Significantly better Global Assessment scores at weeks 2, 4, 6, 8 for BTX-A but no significant difference between groups at week 12.</td>
<td></td>
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</tr>
<tr>
<td>Kocabas et al. (2010) Turkey RCT PEDro=4 TPS=Chronic N=20</td>
<td>20 chronic stroke subjects with severe ankle planter flexor spasticity were randomly assigned to receive a single 5 mL injection of either 5% phenol or 50% ethyl alcohol to the motor branches of tibial nerve. Clinical assessments were performed before Motor branch block, immediately, and at 1, 3, and 6 months after blocking. Assessments included ankle planter flexor spasticity assessed by Modified Ashworth Scale, clonus of the ankle; passive range of motion changes measured by goniometer and motor strength of the ankle planter flexors measured by the Medical Research Council grades 0-5.</td>
<td>In the alcohol group the spasticity score for the ankle planter flexor was reduced in all 10 patients immediately after motor branch block and this was maintained over the 6 month follow up period in 9 patients. In the phenol group the spasticity score for the ankle planter flexor was reduced in all 10 patients immediately after motor branch block and it was maintained over the 6 month follow up period in 7 patients. There were no significant differences between groups on any of the outcomes assessed.</td>
<td></td>
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</tbody>
</table>

9.11.4 Oral Medications
Table 9.1.1 Summary of Studies Evaluating Antispastic Medications

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketel &amp; Kolb (1984)</td>
<td>USA</td>
<td>RCT</td>
<td>PEDro=3</td>
<td>TPS=NA</td>
<td>N=14</td>
<td>14 stroke patients whose spasticity had limited return to function and who had responded to treatment with dantrolene in an initial 6-week study phase were randomly assigned to receive either placebo (n=9) or dantrolene (n=5) for 6 weeks. If patients deteriorated then the blind was broken and they were permitted to resume treatment with dantrolene.</td>
</tr>
<tr>
<td>Medici et al. (1989)</td>
<td>Uruguay</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=NA</td>
<td>N=30</td>
<td>In a double blind study, 30 outpatients with spasticity secondary to stroke were randomly assigned to receive tizanidine or baclofen. Optimal dose per patient was determined by titration of dose level, then optimal dose continued for 30-weeks.</td>
</tr>
<tr>
<td>Katrak et al. (1992)</td>
<td>Australia</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=NA</td>
<td>N=31</td>
<td>In a double-blind, placebo-controlled cross over study, 31 stroke patients with significant motor impairments were randomized to receive either dantrolene sodium or placebo.</td>
</tr>
<tr>
<td>Stamenova et al. (2005)</td>
<td>Germany</td>
<td>RCT</td>
<td>PEDro=8</td>
<td>TPS=3.3±4.4yr</td>
<td>N=120</td>
<td>120 patients with spasticity (scoring 2 or more in at least one joint region on the Ashworth Scale) were randomized to receive 300-900 mg tolperisone daily for 12 weeks, or placebo.</td>
</tr>
</tbody>
</table>

9.11.5 Intrathecal Medications

Table 9.11.5.1 Summary of Studies Evaluating Intrathecal Baclofen

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
In a double-blind cross-over study, 21 stroke patients with intractable spastic hypertonia were randomized to receive either baclofen or normal saline. Those patients who dropped an average of 2 points in either their affected lower extremity side Ashworth or Penn spasm frequency scores were then offered computer-controlled pump implantation or continuous intrathecal baclofen and followed for up to 12 months.

After active drug bolus trial, the average lower and upper extremity Ashworth score on the affected extremities significantly decreased. All active drug scores significantly differed from placebo scores at 6 hours and with up to 12 months of continuous infusion of ITB in 17 patients, the average lower and upper Ashworth scores significantly decreased.

### 9.11.6 Electrical Stimulation

#### Table 9.1.6.1 Summary of Studies Evaluating Electrical Stimulation for Spasticity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meythaler et al. (2001)</td>
<td>USA</td>
<td>RCT PEDro=7 TPS&gt;6mo N=21</td>
<td></td>
<td></td>
<td></td>
<td>After active drug bolus trial, the average lower and upper extremity Ashworth score on the affected extremities significantly decreased. All active drug scores significantly differed from placebo scores at 6 hours and with up to 12 months of continuous infusion of ITB in 17 patients, the average lower and upper Ashworth scores significantly decreased.</td>
</tr>
</tbody>
</table>

### Functional Electrical Stimulation (FES)

- **Cheng et al. (2010)**

  - **Taiwan**
  - **RCT PEDro=6 TPS>3mo N=18**
  - **Methods**: 18 stroke rehabilitation inpatients with spastic foot after stroke were randomly assigned to an experimental (n=9) or a control group (n=9). The experimental group received ES of ankle dorsiflexors in addition to a motor training program that required the subject to dorsiflex the ankles in response to a cue while standing on a rocker board. After 30 minutes of this exercise, subjects received ambulation training focusing on ankle control for 15 minutes. The control group received general range of motion and strength exercises for 30 minutes, followed by 15 minutes of ambulation training focusing on ankle control. Sessions occurred 3 times a week for 4 weeks. Outcomes assessed included dynamic spasticity of plantarflexors, dorsiflexor muscle strength, balance performance, gait kinematics, and functional gait performance as assessed by the Emory Functional Ambulation Profile (EFAP) and were assessed before and after treatment.

- **You et al. (2014)**

  - **China**
  - **RCT PEDro=7 TPS=25.9d TPS=22.7d Nstart=42 Nend=37**

  **Population**: Experimental Group (EG; N=19): Mean age=60.8±10.8yr; Gender: Males=11, Females=8. Control Group (CG; N=18): Mean age=64.1±9.7yr; Gender: Males=10, Females=8.

  **Intervention**: Participants were randomly allocated to either the EG and received functional electrical stimulation (FES) (for 30 minutes/day, 5 days/week, for 3 weeks), or to the CG and received no FES therapy. All patients received standard necessary drugs and rehabilitation, including 60 minutes each of physiotherapy and occupational therapy.

  **Outcomes**

  1. The two groups showed increases in the raw CSS scores after treatment however, the percentage CSS increases in the EG (p<0.05) were significantly less than that in the CG (both p<0.05).
  2. The FMA scores increased after 2 and 3 weeks of treatment, but the percentage increase in the EG (both p<0.05) were much greater than those in the CG (both p<0.05).
  3. The PASS scores increased significantly in
occupational therapy for 5 days per week for 3 weeks. Participants were assessed at baseline (week 0), week 2, and week 3.

**Outcomes:** Composite spasticity scale (CSS); Fugl-Meyer Assessment (FMA); postural assessment scale for stroke patients (PASS); Berg balance scale (BBS); Modified Barthel Index (MBI).

4. The BBS scores of the two groups increased significantly after treatment (p<0.05). No significant difference was found in the increased percentage of the BBS score between the two groups after 2 weeks however, after 3 weeks, the increased percentage of FES group was significantly greater than that of the CG (p<0.05).

5. Both groups improved significantly (p<0.05) on the MBI. The total MBI scores in the FES group increased greater than the CG (p<0.05).

**Bauer et al.** (2015)
Germany
RCT
PEDro=9
TPSes=62d
TPSCG=42d
NStart=37
NEnd=21

**Population:** Functional Electrical Stimulation (FES; N=18): Mean age=64±11yr; Gender: Males=9, Females=9. Control Group (CG; N=19): Mean age=59±14yr; Gender: Males=12, Females=7.

**Intervention:** Patients were randomly allocated to either the FES group and performed active leg cycling with functional electrical stimulation (FES), or to the CG and performed active leg cycling without FES. Both groups cycled for 20 minutes, 3 times/week, for 4 weeks, for a total of 12 sessions. Participants were assessed before the intervention, after the completion of the intervention, and at follow-up 2 weeks after the end of the intervention.

**Outcomes:** muscle power, muscle spasticity, gait velocity: functional ambulation classification (FAC); performance-oriented mobility assessment (POMA); motricity index (MI) (i.e. muscle strength of ankle dorsiflexors, knee extensors, and hip flexors); modified Ashworth scale (MAS); 10-meter walking test (10MWT).

1. Significant improvements between the pre- and post-intervention values were found in both groups for the FAC, POMA and the MI, as well as between the pre-intervention and follow-up values for the same measures.

2. In the follow-up period, there were no significant differences between the two groups at follow-up for the POMA and the FAC. Additionally, there was no statistical difference found between the groups at any time period for the MI [refer to mean values above].

3. During the intervention phase, twice as many patients in the FES group (N=8) became self-ambulatory (FES≥3) than compared to the CG (N=4).

4. The CG walked significantly faster than the FES group at post intervention (p=0.049).

5. There was no significant difference in the 10MWT between the two groups.

6. There was no significant difference in the score change from pre- to post-intervention between the two groups regarding the knee flexors and knee extensors.

**Neuromuscular Electrical Stimulation (NMES)**

**Chen et al.** (2005)
Taipei
RCT
PEDro=4
TPS>1yr
N=24

24 patients, at least one-year post stroke were randomized to receive 20 min of electrical stimulation (ES) daily, 6X/week x 1 month or to placebo ES. Patients were included if they had ankle spasticity of grades 2 or 3 (modified Ashworth scale). Performance on 10 m timed walk was significantly better in the active ES group, 8/12 patients demonstrated a decrease in spasticity compared to only 1/12 patient in the placebo ES group. Although between group differences in walking speed were not reported, patients in the active group demonstrated a significant improvement (89.8 to 80.8 sec), while patients in the control group did not.
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bakhtiary &amp; Fatemy (2008)</td>
<td>Iran</td>
<td>RCT</td>
<td>8</td>
<td>NA</td>
<td>40</td>
<td>40 stroke patients with plantarflexor spasticity were randomized to receive 20 sessions of either 15 min of inhibitory Bobath therapy + 9 minutes of ES on the dorsiflexor muscles or 15 min of Bobath therapy. Outcomes were assessed before and after treatment and included: Passive ankle joint dorsiflexion range of motion, dorsiflexion strength test (graded from 0-no contraction to 5 normal contraction), plantarflexor muscle tone by Modified Ashworth Scale (MAS) and soleus muscle H-reflex. The mean change of passive ankle joint dorsiflexion was significantly greater in the combination therapy group compared with the therapy only group (11.4 vs. 6.1 degrees, p=0.001). The combination therapy group also fared significantly better on MAS and muscle strength mean change: -1.6 vs. -1.1 (p&lt;0.001) and 0.7 vs. 0.4 (p&lt;0.04), respectively. However, no significant change in the amplitude of H-reflex was found between combination therapy (-0.41) and therapy groups (-0.3).</td>
</tr>
<tr>
<td>Mesci et al. (2009)</td>
<td>Turkey</td>
<td>RCT</td>
<td>5</td>
<td>Chronic</td>
<td>40</td>
<td>40 patients with chronic stroke all received a conventional rehabilitation program for a 4-week period. In addition to this rehabilitation program, 20 patients were randomized to receive NMES treatment for hemiplegic foot dorsiflexor muscles for 4 weeks, 5 days a week. The other 20 patients received no additional treatment. Sessions were performed as one session per day and added to a total of 20 sessions. Clinical parameters were evaluated before and after the treatment. Outcomes assessed included ankle passive dorsiflexion ROM, Modified Ashworth Scale (MAS), FIM, Functional Ambulation Categories (FAC), Rivermead Motor Assessment score. There was a significant improvement from pre to post test, favouring the NMES group on the following outcomes: ankle dorsiflexion ROM, MAS score, lower extremity Brunnstrom stage, and FIM score.</td>
</tr>
<tr>
<td>Yamaguchi et al. (2012)</td>
<td>Japan</td>
<td>RCT</td>
<td>8</td>
<td>&lt;6mo</td>
<td>27</td>
<td>27 consecutive stroke rehabilitation inpatients were randomized to one of two experimental groups or a control group. The first experimental group (n=9) received ES of the tibialis anterior and soleus, in addition to passive locomotion-like movement. The second experimental group (n=9) received ES alone. The control group (n=9) received only the passive locomotion-like movement. The single session lasted 20 consecutive minutes. The Modified Ashworth Scale (MAS) was assessed before and immediately after the intervention. There was no statistically significant difference in MAS between the three groups (p=0.23); however, 66.6% of those in the ES plus passive motion group improved MAS scores whereas only 33.3% and 22.2% of those in the ES and passive motion groups improved, respectively.</td>
</tr>
<tr>
<td>Gurcan et al. (2015)</td>
<td>Turkey</td>
<td>RCT</td>
<td>6</td>
<td>TG</td>
<td>32</td>
<td>Population: Experimental Group (EG; N=19): Mean age=57.42±12.51yr; Gender: Males=14, Females=5. Control Group (CG; N=13): Mean age=58.38±12.59yr; Gender: Males=4, Females=9. Intervention: EG received electrical stimulation (ES) 20min/d 5xwk for 3wk in addition to conventional treatment. CG received conventional treatment methods for 3wk. Assessments were conducted at baseline (T0) and post-treatment (T1). Outcome: Brunnstrom Motor Staging (BMS); Modified Ashworth Scale (MAS); Functional Ambulation Scale (FAS); Clonus Score (CS); BMS, FIM, FAS, CS, DSA, MAS, ROM, observed no significant differences between EG and CG at T1. 10MWT significantly increased in EG compared to CG at T1 (p=0.042).</td>
</tr>
</tbody>
</table>
Dorsiflexion Strength of Ankle (DSA); Range Of Motion (ROM); Functional Independence Measure (FIM); 10 Meter Walking Test (10MWT).

**Wang et al.** (2015)  
China  
RCT  
Pedro=6  
TPS$_{EG1}$=32.17±9.10d  
TPS$_{EG2}$=28.86±8.81d  
TPS$_{EG3}$=28.71±8.12d  
TPS$_{CG}$=29.88±9.42d  
N$_{Start}$=72  
N$_{End}$=64  

**Population**  
Experimental Group 1 (EG1; N=17):  
Mean age=49.47±9.44yr; Gender: Males=7, Females=10.  
Experimental Group 2 (EG2; N=16):  
Mean age=49.68±9.75yr; Gender: Males=6, Females=10.  
Experimental Group 3 (EG3; N=17):  
Mean age=50.17±9.80yr; Gender: Males=5, Females=12.  
Control Group (CG; N=16): Mean age=51.81±10.41yr; Gender: Males=5, Females=11.  

**Intervention:**  
EG1 received sensory threshold neuromuscular electrical stimulation (T-NMES) where stimulation was comfortable on the extensor hallucis (EH) and digitorum longus (DL).  
EG2 received motor NMES (M-NMES) in which dorsiflexion movements were observed on the EH and DL.  
EG3 received full-movement NMES (F-NMES) in which dorsiflexion movements were as large as possible on the EH and DL.  
CG received conventional rehabilitation therapy (CRT).  
EG1, EG2, and EG3 received NMES 30min 2x/d, 5d/wk, for 4wk.  
CG, EG1, EG2, and EG3 received CRT.  
Assessments were conducted at baseline (T0), 4wk (T1), and 6wk (T2).  

**Outcomes:**  
Composite Spasticity Scale (CSS); Ankle Active Dorsiflexion (AAD); Timed Up and Go Test (TUGT).  

1. CSS significantly decreased in the EG3 compared to CG, EG1, and EG2 at T2 (p<0.01).  
2. AAD decreased significantly in EG3 compared to CG, EG1, and EG2 and T1 (p<0.05).  
3. TUGT observed no significant differences between CG, EG1, EG2, and EG3 at T1 or T2.  

**Transcutaneous Electrical Nerve Stimulation (TENS)**  

**Levin & Hui-Chan** (1992)  
Canada  
RCT  
PEDro=6  
TPS$_{EG}$=26.4±21.9mo  
TPS$_{CG}$=29.2±17.2mo  
N=13  

13 stroke patients, mean age 59±13.6 years were initially randomized to receive 15 daily TENS treatments (60 min each) over 3 weeks or to a sham treatment. 4 of 6 patients randomized to the TENS group later switched group assignments. Composite spasticity scores were calculated from clinical spasticity scores, maximal H reflex to M response ratios, vibratory inhibition of H reflex, stretch reflexes and maximal voluntary isometric plantarflexion and dorsiflexion, in standing.  
Placebo stimulation produced no significant effects, while repeated applications of TENS over time decreased clinical spasticity and increased vibratory inhibition of the soleus H reflex after 2 weeks. These changes occurred with a substantial improvement in voluntary dorsiflexion force up to 820%, but not plantarflexion force. They were followed by a reduction in the magnitude of stretch reflexes in the spastic ankle plantarflexor, concomitant with a decrease in the EMG co-contraction ratios after a further week of stimulation.  

**Tekeoğlu et al.** (1998)  
Turkey  
RCT  
PEDro=9  
TPS=30-240d  
N=60  

A double blind randomised controlled trial of 60 patients. Patients received either basic neurophysiological rehabilitation or received in addition to the basic neurophysiological rehab treatment, active TENS for 40 sessions over 8 weeks with a frequency of 100Hz at intensity that patients could tolerate.  
At 8 weeks, patients in both groups had significantly improved their BI scores compared to baseline. Patients in the treatment group experienced greater improvement in BI scores compared to the control group. Significant reduction in Ashworth scores was observed in both groups.  

**Ng & Hui-Chan** (2007)  
China  
RCT  

88 patients with chronic stroke were assigned randomly to receive a home-based program of 1) TENS, 2) TENS+ task-related training (TRT), 3) Compared with TENS, the combined TENS+TRT group showed significantly greater improvement in ankle dorsiflexion torque at
<table>
<thead>
<tr>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Study Details</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Chronic</td>
<td>88</td>
<td>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.</td>
<td>Follow-up and in ankle plantarflexion torque at week 2 and follow-up. 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. When compared with all 3 groups, the TENS+TRT group showed significantly greater improvement in gait velocity.</td>
</tr>
<tr>
<td>6</td>
<td>Chronic</td>
<td>62</td>
<td>62 patients, an average of 9.2 days post-stroke, were randomly assigned to 3 groups receiving transcutaneous electrical stimulation (TES), placebo stimulation (PS), or standard rehabilitation (SR) alone. Stimulation was applied to 4 acupuncture points in the affected lower leg for 60 min, 5 days a week for 3 weeks. Plantarflexor spasticity, ankle muscle strength, and functional mobility were measured before treatment, weekly during treatment, and at follow-up at week 8 post-stroke.</td>
<td>Compared with SR or PS groups, a significantly greater percentage of subjects in the TES group experienced achieved normal tone, increased ankle dorsiflexor strength, and decreased antagonist co-contraction ratio compared with the PS or SR groups.</td>
</tr>
</tbody>
</table>
| 5     | Korea | 62 | Population: Transcutaneous electrical stimulation group (TENS; N=22): Mean age=55.2±11.49yr; Gender: Males=14, Females=8. Placebo-TENS group (N=220): Mean age=55.65±8.62yr; Gender: Males=13, Females=7. Intervention: Participants were randomly allocated either to the EG and received transcutaneous electrical stimulation (TENS), or to the CG and received placebo-TENS where the electrodes were placed in the same location (i.e. muscle belly of the gastrocnemius) as in the TENS group but no electrical stimulation was administered. Both groups received physical therapy for 30 minutes before the TENS application. Participants were assessed before the intervention, after the intervention, and one day after the intervention. Outcomes: spasticity, balance: postural sway length (while standing, with eyes open, with eyes closed, on an unstable surface with eyes open); Modified Ashworth Scale (MAS); hand held dynamometer (HHD). | 1. Both the TENS group and the placebo-TENS group demonstrated a significant change in the MAS scores from baseline to post-training, from baseline to follow-up, and from post-training to follow-up (TENS: all p<0.05; Placebo-TENS: all p<0.05). 2. The MAS scores in the TENS group were significantly lower than those in the placebo-TENS group at post-training however, no difference between the two groups was found at follow-up (p<0.05; refer to mean values above) 3. Both the TENS group and the placebo-TENS group demonstrated a significant improvement in HHD from baseline to post-training, and from baseline to follow-up (TENS: all p<0.05; Placebo-TENS: all p<0.05). 4. The HHD was significantly lower in the TENS group compared to the placebo-TENS group at post-training (p<0.05; refer to mean values above). The difference between the two groups was found to be significant at follow-up. 5. TENS with eyes open and eyes closed showed significant improvements in sway length from baseline to follow-up which was not observed in the placebo-TENS group (eyes open: all comparisons p<0.05; eyes closed: all comparisons p<0.05). Only the posttraining values during the eyes closed condition were significantly lower in the TENS group compared to the placebo-
6. During the unstable surface with eyes open condition, both the TENS group and the placebo-TENS group demonstrated a significant difference in postural sway length from baseline to posttraining only (TENS: p<0.05; Placebo-TENS: p<0.05).
7. No other significant difference between groups on outcomes and time points were observed.

Hussain et al. (2013) China RCT PEDro=6 TPSEG=5.01mo TPSCG=4.45mo NStart=35 NEnd=30

**Population:** Experimental Group (EG; N=15): Mean Age=53.6y; Gender: Male=8, Female=7. Control Group (CG; N=15): Mean Age=57.6y; Gender: Male=10, Female=5.

**Intervention:** Control-Bobath therapy. Experimental-Both Bobath and transcutaneous electrical nerve stimulation (TENS) therapy. Both groups received treatment for 4wks, 5d/wk. Bobath therapy-15min passive movement of big toe and remaining toe extension, ankle joint dorsiflexion, knee joint extension and hip joint abduction and external rotation. TENS therapy-30min, delivered through 2 pairs of electrodes attached at acupoints selected according to traditional acupuncture and previous studies.

**Outcomes:** Ankle-joint dorsiflexion range of motion, strength of ankle dorsiflexor muscles, motor function of the lower limb and walking speed: hand-hold goniometer for ankle dorsiflexion, manual muscle strength testing scale for strength of ankle dorsiflexors and the Brunnstrom stage for motor function of lower limb (6 grades-flaccidity, synergy development, voluntary synergistic movement, movements deviating from symmetry, independence from basic synergies and isolated joint movements).

1. Significant increase in ankle passive dorsiflexion range of motion after therapy within both groups (p<0.05) but no significant difference between groups after intervention.
2. MAS showed the second maximally significant mean group value (p=0.001).
3. Parameters were statistically more significant in the EG vs CG.

Park et al. (2014) India RCT PEDro=7 TPSEG=18.6±2.4mo TPSCG=18.5±1.7mo NStart=34 NEnd=29

**Population:** TENS plus therapeutic exercise group (EG; N=15): Mean age=71.2±3.4yr; Gender: Males=8, Females=6. Placebo TENS plus therapeutic exercise group (Placebo; N=14): Mean age=71.1±3.8yr; Gender: Males=12, Females=3.

**Intervention:** EG received TENS exercise plus therapeutic exercise that lasted 30-mins; consisted of a one-to-one ROM exercise (10 min), a functional mat exercise (10 min) and a gait exercise (10 min). The comparator was the Placebo TENS plus therapeutic exercise group (Placebo TENS group).

**Outcomes:** Modified Ashworth scale (MAS).

1. Greater improvements in spasticity denoted by reduced MAS scores were found in the TENS group compared to the placebo group (p<0.05).

Laddha et al. (2016) Population: Mean age=46.46±6.9yr, Gender:
India
RCT
PEDro=5
TPS=15.7±10.1mo
NStart=52
NEnd=30
Males=19, Females=11.

**Intervention:** Participants randomly assigned to receive task oriented exercises alone (CG; N=10), 30min of transcutaneous electrical nerve stimulation (TENS) and task oriented exercises (E1; N=10), or 60min of TENS and task oriented exercises (E2; N=10). All groups completed 5 sessions/wk for 6wk. Outcomes were assessed at baseline, 3wk, and 6wk.

**Outcomes:** Modified Ashworth Scale (MAS); Timed-Up-and-Go Test (TUG).

plantar flexor MAS scores at 6wk in all groups (p<0.05); however, there was a significantly greater improvement in E2, followed by E1 compared to CG (p<0.05).

2. There was a significant improvement in dorsiflexor MAS scores at 6wk in all groups (p<0.05); however, there was a significantly greater improvement in E2, followed by E1 compared to CG (p<0.05).

3. There was a significant improvement in the TUG test over time in all groups (p<0.05); however, there was a no significant difference between groups (p=0.465).

### 9.11.7 Therapeutic Ultrasound

#### Table 9.11.7.1 Summary of Study Evaluating Therapeutic Ultrasound for Spasticity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ansari et al. (2007)</td>
<td>Iran</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&gt;6mo</td>
<td>N=12</td>
<td>12 patients at least 6 months post stroke with ankle plantarflexor spasticity were randomized to continuous therapeutic ultrasound (US) (n = 6) or sham US (placebo) (n = 6) groups. The patients were treated for three days per week, every other day for 15 treatment sessions. Outcomes were assessed before and after treatment including: Hmax/Mmax ratio, Ashworth Scale (AS).</td>
</tr>
</tbody>
</table>

### 9.11.8 Physical Therapy

#### Table 9.11.8.1 Summary of Studies Evaluating Physical Therapy for Spasticity

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design (PEDro)</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bai et al. (2014)</td>
<td>China</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS$_{CG}$=10±5.3d</td>
<td>TPS$_{CG}$=10.20±5.7d</td>
<td>NStart=165</td>
</tr>
</tbody>
</table>
drugs. The CG received standard medications from in hospital ward and at home. **Outcomes:** Modified Ashworth Scale (MAS) at time of enrollment (month 0), end of month 1 and end of month 3, and end of month 6.

**Population:** Robotic Training and physiotherapy (RT; N=36): Mean age=66.5 ±10.6 yr; Gender: Males=21, Females=15. Conventional Physiotherapy (CP; N=71): Mean age=65.4±12.0yr. Gender: Males=42, Females=29.

**Intervention:** The experimental study was robotic training (RT) combined with conventional physiotherapy (CP). The RT that the patients received was the Lokomat, 2 times per week for 6 or more weeks) for at least 30 sessions. The comparator group was conventional physiotherapy (CP). This was a 60-minute program, shared by both groups.

**Outcomes:** modified Ashworth Spasticity Scale (MAS); Berg Balance Scale (BBS); Functional Ambulation Category (FAC).

1. There were no significant differences in the reduction in MAS scores between the groups.
2. The RG demonstrated a significant change from before injections to after 1 month on the maximal gait speed TUG, 6MWT, 6MWT-WO, Time to ascend stairs, and time to descend stairs (all p<0.05). The CG only improved on the time to descend stairs (<0.05).
3. The maximal gait speed, 6MWT, 6MWT-WO, time to ascend stairs, and time to descend stairs from before to after injections were found to be significantly different between the groups (all p<0.05).

**9.12 Alternative Medicine**

**9.12.1 Acupuncture**

Table 9.12.1.1 Summary of Studies Evaluating Acupuncture Therapy

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Country</th>
<th>Study Design</th>
<th>PEDro Score</th>
<th>Time Post Stroke (TPS)</th>
<th>Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Johansson et al.</strong> (1993)</td>
<td>Sweden</td>
<td>RCT</td>
<td>PEDro=5</td>
<td>TPS&lt;10d</td>
<td>N=78</td>
<td>78 stroke patients with severe hemiparesis of the left or right side within 10 days of stroke onset were randomized to either a control group that received daily physiotherapy and occupational therapy or to a group that, in addition to therapy, received sensory stimulation (acupuncture) twice a week for 10 weeks.</td>
<td>There was a significant difference in favor of the group receiving acupuncture in balance, mobility, Activities of Daily Living (ADL) (Barthel Index), quality of life, and days spent at hospitals/nursing homes.</td>
</tr>
<tr>
<td><strong>Gosman-Hedstrom et al.</strong> (1998)</td>
<td>Sweden</td>
<td>RCT</td>
<td>PEDro=7</td>
<td>TPS=Acute</td>
<td>N=104</td>
<td>104 patients were randomized to receive one of three treatments: deep acupuncture treatment; superficial acupuncture treatment; or no acupuncture treatment 2x/wk x 10wks.</td>
<td>No significant differences were found between groups on any of the outcome measures.</td>
</tr>
<tr>
<td><strong>Si et al.</strong> (1998)</td>
<td>China</td>
<td>RCT</td>
<td>PEDro=6</td>
<td>TPS=Acute</td>
<td>N=104</td>
<td>42 inpatients with cerebral infarction confirmed by CT within 7 days of onset with cerebral infarction</td>
<td>While both groups improved in neurological deficits, the experimental group improved</td>
</tr>
</tbody>
</table>

9. Mobility and the Lower Extremity

[www.ebrsr.com](http://www.ebrsr.com)
<table>
<thead>
<tr>
<th>Study</th>
<th>Country</th>
<th>Design</th>
<th>PEDro</th>
<th>TPS</th>
<th>N</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCT</td>
<td></td>
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<td></td>
<td></td>
<td>hemiplegia and muscle strength of limb on hemiplegic side being three out of 6. Patients were randomly assigned to receive either electroacupuncture on the hemiplegic side once a day for 5 days in combination with the drug heparin or to receive the drug only. Significantly more compared to the control group. When comparing every item separately on the Chinese Stroke Scale, the motor shoulder, motor hand and motor leg scores were significantly better in the electroacupuncture plus drug group compared to the drug only group.</td>
</tr>
<tr>
<td>Wong et al. (1999)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>5</td>
<td>7d</td>
<td>42</td>
<td>118 patients were randomized to receive both physiotherapy and occupational therapy or physiotherapy and occupational therapy combined with acupuncture. Improved Brunstrom’s upper limb stage was observed in favour of the acupuncture group compared to therapy only group; as well an improved Brunnstrom’s lower limb stage. Total significant FIM improvement was observed in favor of acupuncture group compared to therapy only group.</td>
</tr>
<tr>
<td>Johansson et al. (2001)</td>
<td>Sweden</td>
<td>RCT</td>
<td>8</td>
<td>2wk</td>
<td>118</td>
<td>150 patients were randomized to receive either acupuncture treatment: high-intensity, low frequency TENS or Subliminal high-frequency transcutaneous electrostimulation. No significant differences were observed between groups on any of the outcome measures (Rivermead Mobility Index, Walking Ability, Barthel Index, Nottingham Health Profile, Nine Hole Peg Test).</td>
</tr>
<tr>
<td>Sze et al. (2002)</td>
<td>China</td>
<td>RCT</td>
<td>7</td>
<td>3-15d</td>
<td>106</td>
<td>106 patients diagnosed with hemorrhagic or ischemic stroke were stratified by Barthel Index scores (BI &lt; 11 or BI &gt;11) and then randomized into a control group (standard treatment) or an intervention group (standard treatment + Chinese manual acupuncture). All patients received 4 to 6 weeks of inpatient rehabilitation. Standard treatment consisted of 60 minute sessions of physical therapy 5 times a week, 45 min sessions of occupational therapy 5 times a week, speech therapy and psychiatric counseling as indicated, and nursing and daily medical rounds. No significant differences were observed between the control group and the intervention group on any of the outcome measures (Fugl-Meyer assessment, Barthel Index, FIM, Abbreviated Mental Test, NIH stroke scale) at 0, 5 and 10 weeks.</td>
</tr>
<tr>
<td>Alexander et al. (2004)</td>
<td>USA</td>
<td>RCT</td>
<td>6</td>
<td>Acute</td>
<td>32</td>
<td>32 patients were randomized to receive standard rehabilitation or standard rehabilitation plus 30 minutes of acupuncture treatment for 14 consecutive days. Fugl-Meyer Assessment (FM) and FIM scores were made. There were no significant differences in either total FM or FIM scores at hospital discharge. However, there were significant differences between groups, favouring acupuncture on two of the FM motor function subscale and the tub/shower transfer subsections of the FIM.</td>
</tr>
<tr>
<td>Fink et al. (2004)</td>
<td>Germany</td>
<td>RCT</td>
<td>6</td>
<td>Chronic</td>
<td>25</td>
<td>Twenty-five patients (14 women) suffering from chronic post stroke leg spasticity with equinovarus deformity (Modified Ashworth Scale [MAS] score, &gt;/=1), aged 38 to 77 years were enrolled in the study. The mean time from stroke to inclusion in the study was approximately 5 years. Participants were randomly assigned to placebo treatment (n=12) by using a specially designed placebo needling procedure, or verum treatment (n=13). MAS, walking speed and pain, measured on a visual analogue scale were assessed. There were no differences in any of the outcome measurements between the two groups. After 4 weeks of treatment, mean MAS scores were 3.3+/-.9 and 3.3+/-.1 in the placebo group and verum group, respectively. The neurophysiologic measure of H-reflex indicated a significant increase of spinal motor neuron excitability after verum acupuncture (H-response/M-response ratio: placebo,.39+/-.19; verum,.68+/-.41; P&lt;.05). The results indicate that needle acupuncture may not be helpful to patients with chronic post stroke spasticity. However, there was neurophysiologic evidence...</td>
</tr>
<tr>
<td>Study</td>
<td>Country</td>
<td>Study Design</td>
<td>PEDro Score</td>
<td>Treatment Duration (TPS)</td>
<td>N</td>
<td>Patients Description</td>
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<tr>
<td>Park et al. (2005)</td>
<td>UK</td>
<td>RCT</td>
<td>9</td>
<td>4 wk</td>
<td>116</td>
<td>Patients with recent onset of stroke (&lt; 4 weeks) were randomized to receive 12 sessions of either real or sham acupuncture for 2 weeks, in addition to multidisciplinary rehabilitation. Outcomes included changes in Barthel Index at the end of treatment, stroke severity and quality of life.</td>
</tr>
<tr>
<td>Hsieh et al. (2007)</td>
<td>China</td>
<td>RCT</td>
<td>8</td>
<td>2 wk</td>
<td>63</td>
<td>Patients admitted to hospital within 2 weeks of stroke onset were randomized to receive a conventional inpatient stroke rehabilitation program with or without 2 courses of electroacupuncture (EA) twice weekly (20 min sessions) for one month. The outcomes of FIM and Fugl-Meyer (FM) Assessments were assessed at 2 and 4 weeks following treatment and at 3 and 6 months.</td>
</tr>
<tr>
<td>Hopwood et al. (2008)</td>
<td>UK</td>
<td>RCT</td>
<td>7</td>
<td>4-10d (TPS)</td>
<td>105</td>
<td>Patients between 4 and 10 days after their first stroke were randomized to receive either 12 acupuncture or placebo treatments over four weeks. Acupuncture with electrical stimulation was compared with mock TENS, and assessments continued for 12 months after entry. Primary outcome was the BI. Secondary outcomes were muscle power, Motricity Index (MI), mood, Nottingham Health Profile (NHP) and treatment credibility.</td>
</tr>
<tr>
<td>Liu et al. (2009)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>7</td>
<td>25-357d (TPS)</td>
<td>30</td>
<td>Patients with stroke onset of 25-357 days, able to ambulate at least 6 meters were randomized into 2 groups and received a single treatment of acupuncture treatment accompanied by the manual twisting of needles until there were sensations of soreness, numbness, swelling and eaviness (experimental group), whereas the control group did not receive manual twisting of needles. Acupuncture stimulation (AS) was applied to a point at the top of the skull (Baihui) as well as to 4 spirit acupoints (1.5 cun anterior, posterior, left and right laterals from the Baihui acupoint, respectively) for 20 min. Balance function was assessed before/after and 10 minutes following treatment using: (1) the displacement area of the patient’s center of gravity; (2) the time taken for a patient to stand vertically from a seated position; (3) the time taken for a patient to walk a distance of 6 meters; (4) muscle strength of the hip flexor and knee extensor muscles of the paralyzed side.</td>
</tr>
<tr>
<td><strong>Zhao et al. (2009)</strong></td>
<td>131 outpatients, mean (SD) age of 59 years, with spastic hemiplegia were randomized to 1 of 2 groups at a mean of 17 months after stroke. Participants received two 30-day treatment regimens of conventional acupuncture or conventional acupuncture + stimulating surface projection zone of decussation of pyramid. Main outcome measures assessed before and after treatment included Modified Ashworth scale (MAS), Fugl-Meyer Assessment (FMA), Barthel Index (BI), and the electromyographic activity of the affected extremity between arms.</td>
<td>There were significantly greater reductions in spasticity, favoring the treatment group in all joints (wrist, elbow, knee, ankle). Improvements in upper and lower FMA scores and BI scores were also significantly greater in the treatment group.</td>
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<tr>
<td><strong>Gao et al. (2012)</strong></td>
<td>106 patients after acute ischemic stroke were assigned to three groups: contralateral needling group received acupuncture on unaffected limbs, conventional acupuncture group that received acupuncture on hemiplegic limbs, and non-acupuncture group that received conventional care. 45 minute acupuncture sessions were administered daily for 30 days. Neurological Deficits Score (NDS), modified Barthel Index (mBI), and FMA were used to assess effectiveness at baseline and after 30 days of treatment.</td>
<td>There was significant decrease in NHS scores in the conventional acupuncture group after treatment when compared with the non-acupuncture group (p&lt;0.01). There was a significant decrease in NDS in the contra-lateral needling group vs. the conventional acupuncture group (p&lt;0.01). There was a significant difference in mBI in contra-lateral acupuncture (p&lt;0.01) vs. conventional acupuncture, and contra-lateral acupuncture vs. non-acupuncture (p&lt;0.01), and conventional acupuncture vs. non-acupuncture (p&lt;0.01). The FMA in contra-lateral needling group was significantly higher than that in conventional acupuncture group (p&lt;0.01) and non-acupuncture group (p&lt;0.01). The FMA was significantly higher in the conventional acupuncture group when compared with the non-acupuncture group (p&lt;0.01).</td>
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<tr>
<td><strong>Hegyi et al. (2012)</strong></td>
<td>50 patients (&lt;6 weeks) after stroke admitted into the rehabilitation ward were randomized into either a treatment group that received acupuncture once a month or a control group that did not receive any form of acupuncture. BI, Rivermead Scale Index (RMI) and Visual Analogue Scale (VAS) were assessed at baseline, discharge from hospital, and at 24 months.</td>
<td>There was a significantly greater increase of BI score in the treatment group when compared with the control group at 24 months (p&lt;0.01). There was a significant improvement in RMI for both treatment and control groups at 24 months (p&lt;0.01). There was significant increase in VAS scores in both groups, with a higher improvement in the treatment group when compared with the control group at 24 months (p&lt;0.05).</td>
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<tr>
<td><strong>Zhuang et al. (2012)</strong></td>
<td>295 ischemic stroke patients, an average of 30 days post ictus were randomly assigned to one of 3 treatment programs each lasting 4 weeks. Patients in all received conventional care as needed—including psychological counseling, standard nursing care, and daily medical evaluation plus (1) acupuncture, (2) physiotherapy, or (3) acupuncture plus physiotherapy. The participants received 60 minutes treatments once a day, 6 days.</td>
<td>Patients in all groups improved over the study period on all of the outcomes assessed, but there were no significant differences in the mean scores among them.</td>
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</table>
Acupuncture needles were left in place for 30 minutes without electrical or manual stimulation. The primary outcomes were the Fugl-Meyer Assessment (FMA), a modified Barthel Index (BI). The Neurologic Defect Scale (NDS) was also assessed. Outcomes were evaluated at baseline, and at 2 and 4 weeks.

### Bai et al. (2013)

**China**

**RCT**

**PEDro=10**

**TPS** = \(40.54 \pm 21.44\)d  
\(TPS_{\text{Acupuncture}} = 37.13 \pm 21.34\)d  
\(TPS_{\text{Combined}} = 42.12 \pm 20.06\)d  
\(N_{\text{Start}} = 120\)  
\(N_{\text{End}} = 120\)

**Population**: Physiotherapy group (N=41): Mean age=59.30±9.66yr; Gender: Males=30, Females=11. Acupuncture group (N=39): Mean age=63.69±8.70yr; Gender: Males=29, Females=10. Combined group (N=40): Mean age=61.65±11.05yr; Gender: Males=25, Females=15.

**Interventions**: Combined physiotherapy and acupuncture. Physiotherapy alone. Acupuncture alone. The acupuncture therapy consisted of a list of main acupoints based on Traditional Chinese Medicine therapy. The physiotherapy program consisted of specific physiotherapies that would help to improve patients’ ADLs (program for atonic stage; Brunnstrom stages 1-2, and a program for spasm stage; Brunnstrom stages 3 to 5)

**Outcomes**: Fugl-Meyer Assessment (FMA); modified Barthel Index (MBI).

1. All treatment groups demonstrated statistically significant within group improvements in FMA scores at Day 28 (M1), as indicated by increases of 65.6%, 57.7%, 67.2%, respectively, relative to Day 0 (M0)
2. At day 56, each of these FMA scores increased by 88.1%, 64.5%, and 88.6% (\(p=0.009\) for FMA_M1 and \(p=0.017\) for FMA_M2), respectively.
3. MBI scores improved for all three groups as indicated by statistically significant increases of 85.2%, 60.4%, and 63.4%, respectively, compared to Day 0.
4. There were no statistically significant differences between the three treatment groups at Day 28, or Day 56.
5. For FMA and MBI scores for the three groups at day 38 compared with day 0 and day 56 compared to day 0. Differences in FMA and MBI scores were not statistically significant between days 0 and day 28 among the groups.
6. Improvements in FMA subscores for lower extremities were not statistically significant 28 days after treatment.
7. FMA scores did not significantly differ among the three groups compared with the baseline FMA on day 0.

### Huang et al. (2014)

**Taiwan**

**Case Control**

**No Score**

**TPS_{\text{EG}} = 36.9±37.9d**  
\(TPS_{\text{CG}} = 32.5±39.4d\)  
\(N_{\text{Start}} = 132\)  
\(N_{\text{End}} = 132\)

**Population**: Experimental Group (EG; N=66): Mean age=63.4±14.4yr; Gender: Males=42, Females=24. Control Group (CG; N=66): Mean age=65.3±13.3yr; Gender: Males=47, Females=19.

**Intervention**: The EG received Acupuncture therapy (and physiotherapy). Conventional rehab was the comparator physiotherapy program in this study. It lasted for 60mins/day, for 5 consecutive days per week.

**Outcome**: Postural Assessment Scale for Stroke patients (PASS) (primary); PASS-MP = maintenance of posture (static); PASS-CP = changes in posture (dynamic).

1. The PASS-MP score in the intervention group was higher than that in the comparator group among ‘low Br-stage’ patients \(\text{[EG}=4.7 \pm 3.7; \text{CG}=2.8 \pm 2.7; p<0.05]\)
2. There were no statistically significant differences in any of the PASS scores between intervention and comparator group among ‘high Br-stage’ patients.
3. Overall, this study revealed no statistically significant improvement of balance in the intervention group.

Note: Brunnstrom stage (Br-stage) indicates how far along a patient has recovered; high and low Br-stage demonstrates variability among patients.
Population: Experimental Group (EG; N=17): Mean Age=49yr; Gender: Male=8, Female=9; Control Group (CG; N=17): Mean Age=51yr; Gender: Male=8, Female=9.

Intervention: Patients in the EG received one session of deep dry needling (DDN) on the spastic leg (fast-in, fast-out technique, 15-20mm penetration into the skin at 1Hz for 25-30s). Patients in the CG received no intervention and were measured twice with 10min of resting in between each measurement.

Outcomes: Pressure pain sensitivity and baropodometry: Modified modified Ashworth Scale (MMAS) for spasticity. Pressure pain thresholds (PPT) assessed bilaterally at the deltoid, second metacarpal and the tibialis anterior muscle through a mechanical pressure algometer. Baropodometry (standing for 1min on force plate, measuring support surface, % of load and force distribution in the fore and rear foot).

1. There was a significant decrease in MMAS scores in the EG after intervention ($\chi^2 = 19.071, P<0.001$, from 41% EG Grade 2, 59% Grade 3 preintervention to 70% Grade 1, 24% Grade 2 and 6% Grade 3 post intervention). There was no change in the CG MMAS scores ($P>0.05$, 59% CG Grade 2 and 41% Grade 3).
2. There was a significant increase in PPT bilaterally for the EG compared to the CG ($P<0.001$). Between group differences of means (experimental PPT-control PPT) of 59.4 in the affected side deltoid, of 88.8 in the affected side metacarpal and 39.7 in the affected side tibialis anterior.
3. Significant group x time x side interactions were observed in the EG for % of load in the forefoot ($F=0.903, p=0.045$), for the support surface in the rear foot ($F=7.675, p=0.006$) and for maximum pressure ($F=1.438, p=0.542$).

Population: Experimental Group (EG, N=7): Mean age=71.71±6.52yr; Gender: Males=4, Females=3. Control Group (CG; N=7): Mean age=58.43±11.63yr; Gender: Males=4, Females=3.

Intervention: EG received acupuncture with a twisting angle less than 90° and blood circulation medication. CG received drugs to improve blood circulation. The acupuncture was given for 30min/d, 5x/wk for 4wk.

Outcomes: Fugl-Meyer Assessment (FMA).

There were no significant differences between the two groups on FMA scores.

Population: 100Hz TEAS group (N=20): Mean age=62.00±9.20yr; Gender: Males=15, Females=5. 2Hz TEAS group (N=20): Mean age=63.50±9.29yr; Gender: Males=16, Females=4. Sham TEAS group (N=20): Mean age=62.45±8.44yr; Gender: Males=15, Females=5.

Intervention: Participants were randomized to receive either 100Hz of transcutaneous electrical acupoint stimulation (TEAS) stimulation on several acupuncture sites (i.e. Hegu, Yuji, Chengshan, and Zusanli), or to receive 2Hz TEAS stimulation on the same sites, or to receive sham TEAS stimulation of 0Hz on the same sites as the real TEAS stimulation. Each session lasted 30 minutes, for a treatment per day, every 4 weeks. Participants were assessed at baseline prior to the treatment period (visit 1), once during

1. The overall performance on all of the outcome measures were not significantly different between the 3 groups.
2. The wrists MAS score correlated significantly with the thumb MAS score ($r=0.360, p=0.005$), the thumb MAS score correlated with the MAS score of the other 4 fingers ($r=0.403, p=0.001$), the thumb MAS scores also correlated significantly with personal hygiene DAS score ($r=0.333, p=0.009$). Furthermore, the MAS score of all 4 fingers correlated significantly with personal hygiene DAS scores ($r=0.357, p=0.005$), and with the posture DAS scores ($r=0.432, p=0.001$). Lastly the BI correlated significantly with the MAS scores of all 4 fingers ($r=-0.312, p=0.015$), and with the GAS ($r=0.518, p=0.0001$).
3. Compared with sham treatment, 100 Hz
every week of the 4 weeks of treatment (visit 2-5), at one month follow-up after the end of the treatment (visit 6), and one again at 2 mo after the end of the treatment period (visit 7).

**Outcomes:** Modified Ashworth scale (MAS); Disability assessment scale (DAS); Holden functional ambulation (HFA); Global assessment scale (GAS); Barthel index (BI).

TEAS significantly reduced wrist MAS score at week 2, 3, 4 of the treatment, and at 1 month after treatment whereas 2 Hz stimulation only decreased wrist MAS score significantly at week 4 of the treatment (all p<0.05) [mean values provided only in graph].

4. 10Hz TEAS reduced wrist MAS scores significantly from baseline at weeks 2, 3, 4 of treatment, and at 1- and 2-month follow-up (all p<0.05).

5. Neither 100 Hz nor 2Hz treatment affected the MAS score of the thumb and the other 4 fingers.

6. A significant effect of intervention (p=0.012), time (p<0.001), and intervention x time interaction (p=0.003) were found, regarding the MAS wrist score indicating that the rate of change in the MAS score over time is different for each treatment group.

7. The Holden score, GAS score, BI, DAS (hygiene, dressing, posture, pain), and MAS (elbow, shoulder, knee, ankle) were not significantly different among groups and across time points.

**Chen et al.** (2016)

China

RCT

PEDro=8

TPS_{EG}=4.53±1.13d

TPS_{CG}=4.48±1.32d

N_{Start}=250

N_{End}=250

**Population:** Experimental Group (EG, N=125): Mean age=62.5±10.60yr; Gender: Males=74, Females=51. Control Group (CG; N=125): Mean age=64.06±10.54yr; Gender: Males=74, Females=51.

**Intervention:** The EG received acupuncture and the CG did not. The acupuncture was given for 2hr/d, 6x/wk for 3wk. The outcomes were assessed at baseline, 1wk, 3wk, and 7wk.

**Outcomes:** National Institute Health Stroke Scale (NIHSS); Fugl-Meyer Assessment (FMA); Bedside Swallowing Assessment (BSA); Videofluoroscopic swallowing study (VFSS); Mini-Mental State Examination; Montreal Cognitive Assessment (MoCA).

1. There was no significant group effect on the NIHSS, FMA, BSA, VFSS, Mini-Mental State Examination, or MoCA between the groups at any time point.

2. There was a significant group by time effect on the NIHSS (p<0.001), VFSS (p<0.001), MMSE (p<0.001), and MoCA (p=0.001), but not on the FMA.

**Liu et al.** (2016)

Taiwan

RCT

PEDro=6

TPS_{EG}=14.9±18.09hr

TPS_{CG}=14.2±19.20hr

N_{Start}=38

N_{End}=31

**Population:** Experimental Group (EG, N=20): Mean age=68.1±9.16yr; Gender: Males=10, Females=10. Control Group (CG; N=18): Mean age=65.6±12.40yr; Gender: Males=14, Females=4.

**Intervention:** EG received manual acupuncture daily for 2wk plus standard care. The CG received only standard care. Outcomes were evaluate at baseline, 4wk and 12wk.

**Outcomes:** National Institutes of Health and Stroke (NIHSS); Fugl-Meyer Assessment (FMA); FIM, BI, or mRS improvement.

1. There were no significant differences between the EG and CG in the NIHSS, FMA, FIM, BI, or mRS improvement at 4wk or 12wk.
9.12.2 Meridian Acupressure

Table 9.1.2.1 Summary of Study Evaluating Meridian Acupressure

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score</th>
<th>Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yue et al. (2013) China RCT PEDro=6</td>
<td>TPS=Chronic N=78</td>
<td>Patients were randomized to receive acupressure led by nurses and routine care, or routine care only. The Barthel Index (BI) and Fugl-Meyer Assessment (FMA) motor scores were assessed at baseline and at the end of the first and third month after stroke.</td>
<td>At the third week, there was a significant difference in BI (p&lt;0.05) and FMA motor scores (p&lt;0.05) between groups, with higher scores in the intervention group.</td>
</tr>
</tbody>
</table>

9.12.3 Chinese Herbal Medicine

Table 9.1.3.1 Summary of Studies Evaluating Chinese Herbal Medicine

<table>
<thead>
<tr>
<th>Author, Year Country Study Design PEDro Score</th>
<th>Time Post Stroke (TPS) Sample Size (N)</th>
<th>Methods</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Goto et al. (2009) Japan RCT PEDro=6</td>
<td>TPS=Chronic N=31</td>
<td>Patients living in two long-term care facilities (mean age = 81.4 years) were randomized to receive tokishakuyakusan (TS; 7.5 g/d, 3x/d, 12mo) or no treatment. Impairments were assessed using the Stroke Impairment Assessment Set (SIAS). Independence was evaluated using the Functional Independence Measure (FIM). For each outcome measure, mean change was calculated every 3mo.</td>
<td>1. From baseline to 12mo, there was no significant deterioration in mean SIAS score in the treatment group, but a significant decline among subjects in the control group (TS:43.6 to 43.3 vs. control: 43.6 to 36.9, p&lt;0.05). 2. The same pattern emerged with FIM scores, whereby mean FIM scores declined in the control group but remained stable in the treatment group. (TS: 66.1 to 66.2 vs. 60.8 to 55.8).</td>
</tr>
<tr>
<td>Kong et al. (2009) Singapore RCT PEDro=8</td>
<td>TPS&lt;1mo N=40</td>
<td>Patients were randomized to receive Neuroaid, a traditional Chinese medicine containing 9 herbal and 5 animal components, or placebo (4 capsules, 3 times a day, for 4 weeks). Fugl-Meyer Assessment (FMA), NIH Stroke Scale (NIHSS), and Functional Independence Measure (FIM) scores were measured at initiation of the treatment, and at 4 and 8 weeks.</td>
<td>1. There were no significant differences between groups on any of the outcome measures at baseline, week 4 or week 8. 2. By week 8, mean FMA and FIM gains in the NeuroAiD® and placebo groups were 16.7 vs. 14.5, p=0.68 and 17.7 vs. 22.6, p=0.12, respectively. 3. Mean NIHSS scores had declined by 2.4 and 3.0 points in the NeuroAiD® and</td>
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<tr>
<td>Study</td>
<td>Country</td>
<td>Study Type</td>
<td>PEDro</td>
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<td>Chen et al. (2012)</td>
<td>Taiwan</td>
<td>RCT</td>
<td>9</td>
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<tr>
<td>Zhu et al. (2014)</td>
<td>China</td>
<td>RCT</td>
<td>6</td>
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<tr>
<td>Chen et al. (2013)</td>
<td>Singapore</td>
<td>RCT</td>
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<tr>
<td>Venketasubramanian et al. (2015)</td>
<td>China</td>
<td>RCT</td>
<td>4</td>
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</table>
EG received Di Huang Yin Zi (DHYZ), an herbal drug, for 2x/d for 12wk. CG received a placebo. Outcomes were evaluated at baseline, 4wk, 8wk, and 12wk.

**Outcomes:** Barthel Index (BI); Fugl-Meyer Assessment (FMA).
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